UnitedHealthcare®

MEDICAL POLICY

GASTROINTESTINAL MOTILITY DISORDERS, DIAGNOSIS AND TREATMENT

Policy Number: 2014T0415M
Effective Date: August 1, 2014

Table of Contents

Related Policies:
Bariatric Surgery

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

COVERAGE RATIONALE

Gastric Electrical Stimulation Therapy

Gastric electrical stimulation therapy is proven and medically necessary for refractory diabetic gastroparesis that has failed other therapies, the treatment of chronic, intractable (drug-refractory) nausea and vomiting secondary to gastroparesis of diabetic or idiopathic etiology when used according to U.S. Food and Drug Administration (FDA) labeled indications. See the U.S. Food and Drug Administration (FDA) section for information regarding FDA labeling and Humanitarian Device Exemption (HDE) for gastric electrical stimulation.

Manometry and Rectal Sensation, Tone, and Compliance Test

The following tests are proven for evaluating anorectal function:

- **Rectal sensation, tone, and compliance test**
- **Anorectal manometry**

Colonic manometry is unproven and not medically necessary for evaluating colon motility.
There is insufficient clinical evidence of efficacy in the published peer-reviewed medical literature for the use of colon motility testing or colonic manometry. Patient selection criteria and the role of colonic manometry in the management of motility abnormalities such as refractory constipation must be better defined in statistically robust, well-designed clinical trials.

Defecography

Defecography is proven and medically necessary for the evaluation of intractable constipation, and for patients with constipation 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) or
- Enterocele (e.g. after hysterectomy) or
- Anterior rectocele

Defecography is unproven and not medically necessary for the routine evaluation of constipation for conditions other than those listed above.
Direct visualization is the preferred method of evaluating intractable constipation in the absence of the stated indications above.

MRI defecography is unproven and not medically necessary for the evaluation of constipation and anorectal or pelvic floor disorders.
There is insufficient clinical evidence of efficacy in the published peer-reviewed medical literature for the use of MRI defecography. The utility of this advanced imaging technology in the evaluation and management of refractory constipation must be better defined in statistically robust, well-designed clinical trials.

Electrogastrography and Electroenterography

Cutaneous, mucous, or serosal electrogastrography or electroenterography is unproven and not medically necessary for diagnosing intestinal or gastric disorders including gastroparesis.
There is insufficient evidence to conclude that electrogastrography or electroenterography can accurately diagnose gastroparesis and other gastric or intestinal disorders. There are no data to conclude that electrogastrography or electroenterography is beneficial for health outcomes in patients with gastric or intestinal disorders.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-

covered health service. Coverage is determined by the enrollee specific benefit 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 claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT® Code	Description
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 or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral or gastric neurostimulator pulse generator or receiver
76496	Unlisted fluoroscopic procedure (eg, diagnostic, interventional)
76498	Unlisted magnetic resonance procedure (eg, diagnostic, interventional)
91117	Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distension, pharmacologic agents, if performed), with interpretation and report
91120	Rectal sensation, tone, and compliance test (ie, response to graded balloon distention)
91122	Anorectal manometry
91132	Electrogastrography, diagnostic, transcutaneous;
91133	Electrogastrography, diagnostic, transcutaneous; with provocative testing
95980	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, without reprogramming
95982	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; subsequent, with reprogramming

DESCRIPTION OF SERVICES

Gastroparesis, also referred to as gastric stasis, is a common gastrointestinal motility disorder. It is defined by delayed gastric emptying without evidence of mechanical obstruction. Patients 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 involves upper endoscopy to visualize any macroscopic anomalies. After 12 hours of fasting, the patient drinks barium-containing liquid, which coats the stomach and renders it visible on x-ray. If food is detected in the stomach, it is an indication that gastric emptying is delayed. Gastric emptying is then documented by scintigraphic analysis. The patient ingests a radioactively labeled meal, and the amount of radioactivity detected in the stomach is used to calculate the retention of the test meal over time. This is compared with the known gastric emptying rate of normal subjects to identify patients whose gastric emptying is delayed. Limitations of gastric emptying scintigraphy include lack of standardization of meal composition, timing of image acquisition, and lack of appropriate normal values with some meals.

A common method to measure colonic transit in patients with constipation is the radiopaque marker test (Locke, American Gastroenterological Association Medical Position Statement, 2000). This test is accomplished by observing the passage of orally administered radiopaque markers on abdominal x-ray. Radiopaque markers provide only a qualitative assessment (normal or abnormal) of colon transit, require at least 2 separate visits, and are associated with radiation exposure.

Electrogastrography (EGG is the recording and the interpretation of gastric electrical activity. Recordings can be made from the gastrointestinal mucosa, serosa, or skin surface (cutaneous). Cutaneous electrogastrography records gastric myoelectrical activity from the surface of the body by using surface electrodes. Although it has been reported that EGG reflects the frequency of internal gastric myoelectrical activity, there is not acceptable correlation with gastric contractions or gastric emptying. Electroenterography is a similar procedure that records myoelectrical activity from the intestines.

Anorectal manometry is a test that measures the pressures of the anal sphincter muscles, the sensation in the rectum, and the neural reflexes needed for normal bowel movements. This test is has been used to evaluate patients with constipation or fecal incontinence. The rectal sensation, tone, and compliance test measures the sensory, motor and biomechanical function of the rectum.

Colon motility testing or colonic manometry is the recording of intraluminal pressures from within the large bowel by means of a manometric catheter. The catheter is positioned endoscopically and clipped to the colonic mucosa. Pressure activity is continuously recorded for a minimum of six hours. This test has been proposed to evaluate motility abnormalities and defecation disorders such as constipation.

Electrical stimulation of the gastric musculature**,** also called gastric pacing, has been introduced as an alternative to drugs or surgery for treatment of patients with gastroparesis. It has been hypothesized that electrical stimulation of the gastric musculature could result in paced, coordinated gastric contractions similar to those seen occurring at approximately 3 cycles per minute (cpm) in the normal stomach.

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. Defecography has been proposed as a diagnostic tool to evaluate lower bowel disorders that are not evident by direct visualization. Magnetic resonance imaging (MRI) of defecation (also known as MR defecography, magnetic resonance defecography, MRI defecography, dynamic magnetic resonance imaging of defecation, and dynamic MR proctography), 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.

CLINICAL EVIDENCE

Gastric Electrical Stimulation (GES) Therapy

Chu et al. (2012) conducted a meta-analysis to assess the effects of gastric electrical stimulation (GES) on symptoms and gastric emptying in patients with gastroparesis, and the effects of GES on the three subgroups of gastroparesis. Data on the total symptom severity score (TSS), nausea severity score, vomiting severity score, and gastric emptying were extracted and analyzed. The statistic effect index was weighted mean differences. Ten studies (n = 601) were included in the meta-analysis. In the comparison to baseline, there was significant improvement of symptoms and gastric emptying. It was noted that GES significantly improved both TSS and gastric retention at 2 hours and 4 hours in patients with diabetic gastroparesis (DG), while gastric retention at 2 hours in idiopathic gastroparesis (IG) patients, and gastric retention at 4 hours in postsurgical gastroparesis (PSG) patients, did not reach significance. Based on this meta-analysis, the authors concluded that the substantial and significant improvement of symptoms and gastric emptying, and the good safety indicate that high-frequency GES is an effective and safe method for treating refractory gastroparesis. DG patients seem the most responsive to GES, both subjectively and objectively, while the IG and PSG subgroups are less responsive and need further research.

A meta-analysis was performed to evaluate evidence for improved clinical outcome with gastric electrical stimulation. A literature search of major medical databases was performed for the period January 1992 to August 2008. Clinical studies involving an implanted high-frequency GES device were included and reported a range of clinical outcomes. Studies of external, temporary, and/or low-frequency GES were excluded. Of 13 included studies, 12 lacked controls and only one was blinded and randomized. Following GES, patients reported improvements in total symptom severity score (3/13 studies), vomiting severity score (4/13 studies), nausea severity score (4/13 studies), SF-36 physical composite score (4/13 studies), SF-36 mental composite score (4/13), requirement for enteral or parenteral nutrition (8/13), and 4-h gastric emptying (5/13 studies). Weight gain did not reach significance (3/13 studies). The device removal or reimplantation rate was 8.3%. The authors concluded that results show substantial benefits for high-frequency GES in the treatment of gastroparesis. However, caution is necessary in interpreting the results, primarily because of the limitations of uncontrolled studies. According to the authors, further controlled studies are required to confirm the clinical benefits of high-frequency GES (O'Grady et al., 2009).

McCallum et al. (2010) performed a controlled, multicenter, prospective study to evaluate the safety and efficacy of Enterra therapy in 55 patients with chronic intractable nausea and vomiting from diabetic gastroparesis (DGP). After surgery, all patients had the stimulator turned on for 6 weeks and then they randomly were assigned to groups that had consecutive 3-month, cross-over periods with the device on or off. After this period, the device was turned on in all patients and they were followed up, unblinded, for 4.5 months. The median reduction in weekly vomiting frequency (WVF) at 6 weeks, compared with baseline, was 57%. There was no difference in WVF between patients who had the device turned on or off during the cross-over period (median reduction, 0%). At 1 year, the WVF of all patients was significantly lower than baseline values (median reduction, 67.8%). The investigators concluded that in patients with intractable DGP, 6 weeks of GES therapy with Enterra significantly reduced vomiting and gastroparetic symptoms.

Patients had improvements in subjective and objective parameters with chronic stimulation after 12 months of GES, compared with baseline.

McCallum et al. (2011) assessed the long-term clinical outcomes of gastric electrical stimulation (GES) therapy with Enterra® in a large cohort of patients with severe gastroparesis. Gastroparesis patients (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.

Abell et al. (2002) reported on a group of 38 patients with drug-refractory gastroparesis who were implanted with the Enterra system. After one year, their symptoms of gastroparesis were significantly reduced. After 12 months, gastric emptying had improved in most patients, and 9 out of 14 patients receiving enteral or parenteral nutrition were able to discontinue it. In a follow-up study of a subgroup of 12 patients, Abell et al. (2003a) report these results lasted as long as 5 years. In a randomized, double-blinded study of 33 patients, Abell et al. (2003b) reported a reduction in symptom scores and dependence on enteral and parenteral feeding.

In a retrospective analysis of 214 patients, there was no significant difference in survival rates between patients who underwent GES and 54 historical controls. However, for patients with diabetes, there was a significant survival benefit for those who received permanent GES versus patients who received standard medical treatment. The 36-month survival rate was 60.7% for gastric stimulation compared with 33.3% in the medical therapy group. At the last follow-up (median, 4 years), significant improvements were reported in vomiting (62%), nausea (59%), and total symptom (84%) (Anand et al. 2007).

Musunuru et al. (2010) evaluated the use of gastric electrical stimulation (GES) therapy in 15 patients. Four patients with idiopathic gastroparesis failed to improve more than 20% on multiple assessments after a year of therapy. All diabetic patients experienced a durable symptomatic improvement with GES. The investigators concluded that diabetic gastroparesis patients respond best to GES. Responders tend to have more severe vomiting preoperatively. According to the investigators, patients with idiopathic gastroparesis who do not experience severe vomiting should be cautioned about a potentially higher rate of poor response to GES and may be better served with alternative treatments.

Professional Societies

The American College of Gastroenterology (ACG): The ACG published a clinical guideline for the management of gastroparesis that states that gastric electrical stimulation (GES) may be considered for compassionate treatment in patients with refractory symptoms, particularly nausea and vomiting. According to the guideline, symptom severity and gastric emptying have been shown to improve in patients with diabetic gastroparesis (DG), but not in patients with idiopathic gastroparesis (IG) or post-surgical gastroparesis (PSG). (moderate level of evidence) (Camilleri 2013).

American Gastroenterological Association (AGA): In a 2004 medical position statement, the AGA indicated that the primary treatment of gastroparesis includes dietary manipulation and

administration of antiemetic and prokinetic agents; however gastric electric stimulation is an emerging therapy for refractory gastroparesis. The AGA medical position statement does not mention the use of electrogastrography (Parkman, 2004 medical position statement). In the 2004 technical review on the diagnosis and treatment of gastroparesis, the AGA states that clinically, electrogastrography (EGG) has been used to demonstrate gastric myoelectric abnormalities in patients with unexplained nausea and vomiting or functional dyspepsia. EGG is considered an adjunct to gastric emptying scintigraphy as part of a comprehensive evaluation of patients with refractory symptoms suggestive of an upper gastrointestinal motility disorder. However, to date, there has been little investigation to validate the utility of EGG in the management of patients with suspected gastric dysmotility (Parkman, 2004 technical review).

Anorectal Manometry
Noviello et al. (2009) evaluated the role of anorectal manometry (ARM) in 85 children with severe constipation. The mean age was 5 years (range, 1-13). Based on the results of the study, the investigators concluded that ARM is a noninvasive diagnostic tool to study the mechanism of defecation in children with constipation in order to prescribe the appropriate treatment. This procedure can be used in every child, aged more than 1 year, with severe constipation. The authors concluded that assessment of the recto-anal inhibitory reflex (RAIR) can select the cases for rectal suction biopsies (RSB).

Pucciani and Ringressi (2012) evaluated the clinical usefulness of anorectal manometry (AM) in patients affected by obstructed defecation (OD). A total of 379 patients (287 women and 92 men) affected by OD were evaluated. After a preliminary clinical evaluation, defecography and AM were performed. The results were compared with those from 20 healthy control subjects. Overall anal resting pressure was not significantly different between patients and controls. Maximal voluntary contraction (MVC) data were significantly lower when compared with those of controls. The straining test was considered positive in 143 patients. No significant difference was noted between patients and controls in maximal tolerated volume data. Patients had a significantly higher conscious rectal sensitivity threshold than controls. According to the authors, a positive straining test, low MVC and impaired rectal sensation are the main abnormalities detected by AM in patients with OD.

Muñoz Yagüe et al. (2003) evaluated the role of the clinical, anorectal manometry and surface electromyography in the assessment of patients with fecal incontinence. Ninety-three patients with fecal incontinence were reviewed and data was obtained from the clinical history, physical examination of the anal region, digital rectal examination, anorectal manometry and surface electromyography. Treatment was administered in accordance with the alterations encountered and the results evaluated at 3 and 12 months. The anorectal manometry (ARM) demonstrated some alterations in 90.3% of the patients, whereas a hypotonic sphincter was the most common finding (85.7%). Rectal sensitivity or distensibility alterations were present in the rest of the patients. In 79.2% of the cases, hypotonic sphincter was associated with rectal sensitivity or distensibility alterations. In 65.2% of patients with hypotonic external anal sphincter, damage of the pudendal nerve was found. According to the investigators, the clinical study of the patients, together with the anorectal manometry and surface electromyography enables the identification of the cause of FI and its treatment.

Professional Societies
The American Society of Colon and Rectal Surgeons: In a practice parameter for the treatment of fecal incontinence, the American Society of Colon and Rectal Surgeons indicates that anorectal physiology studies (anal manometry) may be helpful in guiding management of fecal incontinence (Tjandra et al., 2007).

In a practice parameter for the evaluation and management of constipation the American Society of Colon and Rectal Surgeons indicates that anorectal manometry and surface anal electromyography may help to confirm pelvic floor dyssynergia or anismus. The presence of

Hirschsprung's disease also can be suggested by anorectal manometry when the rectoanal inhibitory reflex is absent (Ternent et al., 2007).

American Gastroenterological Association (AGA): an AGA guideline on constipation states that anorectal manometry and a rectal balloon expulsion should be performed in patients who fail to respond to laxatives (strong recommendation, moderate-quality evidence). (AGA 2013).

Colonic Motility Testing or Colonic Manometry
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.

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.

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. (2004) 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. These findings require confirmation in a larger study.

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.

Based on colonic manometries that showed either no contractions or an absence of the gastrocolonic response or an absence of high-amplitude propagating contractions, diverting colostomies or ileostomies were recommended in 12 chronically constipated children (mean age, 4 years; range, 2-14 years, 5 boys). Before study, medical treatment was ineffective in all children. These children had persistently dilated colons with pathologic diagnoses of intestinal neuronal dysplasia (n = 4), hypoganglionosis (n = 2), hollow visceral myopathy (n = 1), and normal (n = 5). Six to 30 months after diversion, the investigators restudied all the children. Eleven of 12 diverted colons were no longer dilated. In two patients, abnormal motility involving the entire colon was unchanged from the initial study, small bowel motility was abnormal, and the investigators recommended no further surgery. In two cases, the colon remained abnormal but small bowel motility was normal, and the investigators recommended subtotal colectomy and ileoproctostomy. In four cases, the left colon remained abnormal, but the right colon was normal, and the investigators recommended reanastomosis after left hemicolectomy. In four cases, motility in the diverted colons was normal, including a gastrocolonic response and high-amplitude propagating contractions, and the investigators recommended reanastomosis. Defecation problems resolved in 10 of 12 when followed up 5 to 30 months after treatment. According to the investigators, these data suggest that in some cases of intractable childhood constipation associated with colonic distention, temporary diversion improved colonic motility. Colonic manometry may be used to predict which patients will benefit from resection or reanastomosis (Villarreal et al. 2001). These findings require confirmation in a larger study.

Di Lorenzo et al. (2000) evaluated 46 symptomatic patients (5.5+/-3.3 years old, 35 male) >10 months after surgery for Hirschsprung's disease. Four motility patterns were identified based upon the results from colonic manometry: 1) high-amplitude propagating contractions (HAPCs) associated with fecal soiling (n = 18); 2) normal colonic manometry associated with fear of defecation and retentive posturing (n = 9); 3) absence of HAPCs or persistent simultaneous contractions over two or more recording sites (n = 15), associated with constipation (n = 13); and 4) normal colonic motility and a hypertensive internal anal sphincter (n = 4). When treatment was based on results of the motility studies, there was improvement in global health and emotional health. Improvement in the number of bowel movements occurred in 72% of children. Resolution or decreased abdominal pain was reported in 80%. The investigators concluded that colonic

manometry clarifies the pathophysiology and directs treatment in symptomatic children after surgery for Hirschsprung's disease. The lack of a control group limits the validity of the results of this study.

Di Lorenzo et al. (1992) evaluated colon manometry as a means of differentiating causes of intractable constipation in 23 children. Based on the results of the study, the investigators concluded that in children with severe chronic constipation the colonic results of manometry differentiate patients with functional fecal retention from those with neuropathy or myopathy of the colon. This was an uncontrolled trial with a small study population.

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% o 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.

Martin et al. (2004) evaluated total colonic manometry performed on 9 patients referred for surgical evaluation of refractory functional colonic obstruction. According to the authors, surgical management was guided by TCM results. There was significant improvement in bowel function and weight gain after manometry-guided intervention. An unnecessary laparotomy was avoided in 2 patients. The authors concluded that TCM can be valuable in deciding the need for and timing of diversion, the extent of resection required, and the suitability of the patient for restoring bowel continuity in refractory functional obstruction. However, this study is limited by an extremely small sample size.

Wiklendt et al. (2013) evaluated an automated analysis technique of colonic manometry data that was developed to differentiate the motor patterns of 17 patients with slow transit constipation (STC) from those recorded in 14 healthy controls. According to the authors, manual analysis of data acquired from manometric studies of colonic motility is laborious, subject to laboratory bias and not specific enough to differentiate all patients from control subjects. The authors found that automated analysis of colonic manometry data using cross-correlation separated all patients from controls. This study is limited by a small sample size.

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.

Professional Societies

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 regards to patient's values and preferences (AGA 2013).

According to the American Gastroenterological Association's Technical Review on Constipation, colonic manometry or barostat-manometric testing should be considered in patients with medically refractory slow transit constipation (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. 2013).

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition: According to the recommendations from the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition, rectal biopsy with histopathologic examination and rectal manometry are the only tests that can reliably exclude Hirschsprung disease. Colonic manometry, by providing objective evidence of colonic function, can exclude the presence of underlying neuropathy or myopathy and may guide therapeutic intervention (North American Society for Pediatric Gastroenterology, Hepatology and Nutrition 2006).

American Neurogastroenterology and Motility Society (ANMS): (Camilleri, 2008): The ANMS consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice states that the impact of colonic motility testing to identify significant colonic dysmotility versus multiple failed therapeutic trials on outcomes to surgery and patient preference has not been formally compared in adult patients. The consensus statement also indicates that the measurement of colonic motility and tone is established as a valid clinical tool to facilitate the management of significant motility disorders in adult and pediatric practice. According to the ANMS, indications for intraluminal colonic motility measurements include the following:

- Assess patients with severe constipation, unresponsive to medical therapy, and associated with slow colonic transit and no evidence of an evacuation disorder
- Confirm chronic megacolon or megarectum in patients whose viscus diameters exceed 10 and 15 cm respectively
- Clarify the pathophysiology of persistent symptoms after removal of the aganglionic segment in children with Hirschsprung's disease
- Evaluate the function of a diverted colon before possible closure of a diverting ostomy
- Predict the response to antegrade enemas via cecostomy

The ANMS also states that studies performed in large motility centers using both the antegrade and the retrograde approach have suggested that colonic manometry can be used in children to:

- Select medical and surgical treatment when conventional medical and behavioral treatments have failed (Pensabene 2003, Martin 2004)
- Clarify the pathophysiology of persistent symptoms after removal of the aganglionic segment in children with Hirschsprung's disease (Di Lorenzo 2000)
- Evaluate the function of a diverted colon before possible closure of a diverting stoma (Villarreal 2001)
- Predict the response to antegrade enemas via cecostomy (van den Berg 2006)

Conventional Defecography
Clinical evidence supports the use of conventional defecography for evaluating intractable constipation. Defecography is helpful for identifying anatomic abnormalities and conditions that are suspected to be the cause of impaired defecation including sphincter defect, rectocele, enterocele, and intussusception (Tomita, 2010; Groenendijk, 2008; Dobben, 2005; Savoye-Collet, 2005; Rao, 2005).

Professional Societies
American Gastroenterological Association (AGA): In a technical review on anorectal testing techniques, the AGA (1999) states that defecography can identify structural and functional alterations including rectocele, internal rectal intussusception, external rectal prolapse, enterocele and pelvic floor dysfunction or dyssynergia. AGA recommends that conventional defecography is of potential value in patients with constipation when the following conditions are suspected as the cause of impaired defecation:

- pelvic floor dyssynergia (inappropriate contraction of the puborectalis muscle)
- enterocele (e.g., after hysterectomy)
- anterior rectocele (e.g., history of manipulation of the rectal wall per vagina)

The 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) (AGA 2013).

According to the American Gastroenterological Association'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. 2013).

American College of Gastroenterology (ACG): The ACG practice guidelines on fecal incontinence states that conventional defecography is useful in patients with suspected rectal prolapse or in those with poor rectal evacuation, but it is otherwise of limited value (Rao, 2004).

American Society of Colon and Rectal Surgeons (ASCRS): In the ASCRS guideline for the evaluation and management of constipation, the authors state that conventional defecography is probably the most useful technique for identifying internal rectal intussusception. Defecography may also be useful in detecting structural causes of obstructed defecation such as rectocele with retained stool, pelvic dyssynergia, and extent of rectal emptying in the presence of obstructed defecation. Lack of rectocele emptying on defecography may be an indication for surgical repair of rectocele (Ternent, et al., 2007).

In a practice parameter for the management of rectal prolapse, the ASCRS states that defecography is one of several tests that can be used selectively to define the diagnosis and identify other important pathologies (Grade of Recommendation: Strong recommendation based on moderate-quality evidence 1B). Defecography may also identify associated defects such as cystocele, vaginal vault prolapse, and enterocele (Varma, et al., 2011).

MRI Defecography
Foti et al. (2013) prospectively compared the diagnostic capabilities of magnetic resonance (MR) imaging with conventional defecography (CD) in outlet obstruction syndrome in 19 patients.

Comparison between CD and MR with evacuation phase (MRWEP) showed no significant differences in sphincter hypotonia, dyssynergia, rectocele or rectal prolapse and significant differences in descending perineum. Comparison between CD and MR without evacuation phase (MRWOEP) showed no significant differences in sphincter hypotonia, dyssynergia or enterocele but significant differences in rectocele, rectal prolapse and descending perineum. Comparison between MRWEP and MRWOEP showed no significant differences in sphincter hypotonia, dyssynergia, enterocele or descending perineum but significant differences in rectocele, rectal prolapse, peritoneocele, cervical cystoptosis and hysteroptosis. The authors concluded that MR imaging provides morphological and functional study of pelvic floor structures and may offer an imaging tool complementary to CD in multicompartment evaluation of the pelvis. The findings of this study need to be validated by well-designed studies with larger sample sizes.

Vitton et al. (2011) compared the accuracy of dynamic anorectal endosonography and dynamic MRI defecography with conventional defecography as the criterion standard in the diagnosis of pelvic floor disorders. The study was a prospective crossover design in which 56 patients with dyschezia underwent each procedure in random order by 3 blinded operators within the same month. No significant differences were observed between dynamic anorectal endosonography and dynamic MRI in the number of patients with rectocele, perineal descent, or enterocele. Diagnostic concordance with conventional defecography as the standard did not differ significantly between dynamic MRI and dynamic anorectal endosonography: concordance rates for dynamic MRI were 82% for rectocele, 57% for perineal descent, 93% for enterocele, and 55% for rectal intussusception. Significantly more internal anal sphincter defects were found with dynamic anorectal endosonography than with dynamic MRI defecography. Patient tolerance was significantly better for dynamic anorectal endosonography than for dynamic MRI or conventional defecography.

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. 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%.

Otto et al. (2011) assessed the correlation of conventional defecography and MR-defecography after rectopexy in 21 patients. According to the authors, both methods revealed consistent results with respect to anorectal angle and perineal motility. The authors also stated that the concomitant depiction of structures in MR-defecography is helpful in the assessment of descent of pelvic organs and permits visualization of enteroceles. However, in 30% of patients, MR-defecography wrongly showed incomplete evacuation.

The utility of this advanced imaging technology in the evaluation and management of refractory constipation must be better defined in statistically robust, well-designed clinical trials.

Professional Societies

The 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 (AGA 2013).

The American College of Gastroenterology (ACG): The ACG practice guidelines on fecal incontinence (Rao, 2004) noted that MR defecography may more precisely define the anorectal anatomy, but comparative studies are needed to determine clinical utility and how this test would influence treatment decisions.

Electrogastrography (EGG) or Electroenterography
O'Grady et al. (2012) applied high-resolution electrical mapping to quantify and classify gastroparesis slow-wave abnormalities in spatiotemporal detail. Serosal high-resolution mapping was performed using flexible arrays at stimulator implantation in 12 patients with diabetic or idiopathic gastroparesis. The authors found that intraoperative 256 electrode serosal recordings in gastroparetics revealed abnormal slow wave initiation, reduced velocities, conduction blocks, and increased amplitudes undetectable on cutaneous recordings. According to the authors, this reflects relative insensitivity of clinical EGG methodologies.

Chen et al. (1996) performed both EGG and scintigraphic emptying in 97 patients with symptoms suggestive of gastroparesis. The investigators found that abnormalities in the postprandial EGG seem to be able to predict delayed emptying of the stomach. However, a normal EGG does not seem to guarantee normal emptying of the stomach.

Frasko et al. (2008) conducted a prospective study to characterize the disturbance of gastric electrical control activity in different types of ileus and to correlate surface electrogastrography (EGG) findings with a set of inflammatory markers. Fifty-four adult patients with mechanic, vascular and paralytic ileus proven on clinical and radiological exams and 14 age- and sex-matched controls were examined. Irregular EGG activity without a dominant frequency or bradygastria was seen in all patients with both vascular and paralytic ileus and in 67.86% of the patients with obstructive ileus. According to the investigators, EGG examination confirmed a high sensitivity in the evaluation of gastric electrical control activity in both vascular and paralytic ileus. This study failed to show how EGG would impact patient management or disease outcomes.

Chen et al. (2005) assessed the gastric myoelectrical functioning in 20 patients with Parkinson's disease (PD) and in 11 healthy controls by using EGG and determined the clinical utility of EGG in differentiating PD patients with or without upper gastrointestinal symptoms. The PD patients were stratified into two subgroups: 9 were assessed as PD without upper gastrointestinal symptoms (group A) and 11 as PD with upper gastrointestinal symptoms (group B). The investigators concluded that gastric myoelectrical activity is impaired in both groups of PD patients and that EGG appears to have a limited, if any, clinical utility in the differentiation of PD patients with or without upper gastrointestinal symptoms.

Bentur et al. (2006) investigated EGG abnormalities in 23 cystic fibrosis (CF) patients and examined whether EGG correlates with gastric emptying as assessed by scintigraphy. Pre- and postprandial EGG indexes were compared to 19 healthy control patients. Gastric emptying was assessed simultaneously by gastric scintigraphy in 11 of the 23 CF patients. Abnormal patterns of EGG were found in 78.3% of CF patients compared to 31.3% of controls during fasting and in 56.5% of CF patients compared to 15.7% in healthy controls postprandially. Gastric emptying results on scintigraphy were in agreement with EGG results in 9 of 11 (two normal and seven pathological). Five of the six patients treated with cisapride (83.3%) showed significant improvement in EGG indexes. According to the investigators, the similar rate of EGG and gastric scintigraphy abnormalities suggests that EGG may be a useful clinical tool in CF patients. This study is limited by a small sample size.

Sha et al. (2009) evaluated 31 patients with functional dyspepsia who were assessed for severity of upper gastrointestinal symptoms with EGG and antroduodenal manometry. The EGG was abnormal in 71.0% of patients. Antral motility was abnormal in 80.6% of patients and duodenal motility was abnormal in 74.2% of patients. No one-to-one correlation was noted between the symptom scores and any of the EGG or motility parameters. The investigators concluded that

more than two-thirds of patients with functional dyspepsia have abnormalities in the EGG and antral/duodenal motility. The sensitivity of these 2 different methods is essentially the same. EGG and antroduodenal manometry can complement each other in demonstrating gastric motor dysfunction in patients with functional dyspepsia. These findings require confirmation in a larger study.

Lin et al. (2010) investigated the association between the status of interstitial cells of Cajal (ICC) and electrogastrogram (EGG) parameters, gastric emptying, and symptoms in a cohort of patients with gastroparesis. Forty-one patients with refractory gastroparesis who were referred for gastric electrical stimulation (GES) underwent full thickness gastric (antrum) biopsy during the surgery to place the GES device. The biopsy samples were stained with c-kit and scored for the presence of ICC based on criteria obtained from 10 controls. All patients underwent EGG recordings, a 4-hour standardized scintigraphic gastric emptying study and symptom assessment prior to the surgery. According to the investigators, the study suggested that the EGG may have a role for predicting ICC status during clinical evaluation of gastroparetic patients. However, this study failed to show how EGG would impact patient management or disease outcomes.

The studies of electrogastrography failed to provide convincing evidence that this technique is accurate for diagnosis of gastric disorders such as gastric stasis or that it has a positive impact on patient management or disease outcome. Additional studies are needed to determine if electrogastrography 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. No studies were found that indicated that electroenterography has a positive impact on patient management or disease outcome.

The clinical evidence was reviewed in April 2014 with no additional information identified that would change the conclusion.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Instruments to perform cutaneous electrogastrography are regulated by the FDA as Class II devices. See the following Web site for more information (Use product code MYE or FFX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed April 19, 2014.

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. An HDE application is not required to contain the results of scientifically valid clinical investigations demonstrating that the device is effective for its intended purpose. The application, however, must contain sufficient information for the FDA to determine that the device does not pose an unreasonable or significant risk of illness or injury, and that the probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment. Additionally, the applicant must demonstrate that no comparable devices are available to treat or diagnose the disease or condition, and that they could not otherwise bring the device to market. The labeling must state that the effectiveness of the device for the specific indication has not been demonstrated.
See the following Web site for more information:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=H990014
Accessed April 19, 2014.

HDE is a special regulatory marketing approval that makes the device available on a limited basis provided that: (1) The device is to be used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) the device would not be available to a

person with such a disease or condition unless the exemption is granted; (3) no comparable device (other than a device that has been granted such an exemption) is available to treat or diagnose the disease or condition; and (4) the device will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

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) [Web site] - Center for Devices and Radiological Health (CDRH) at: http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/HDEApprovals/ucm161827.htm. Accessed April 19, 2014.

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. The manufacturer states that the safety of the Enterra device has not been established for patients who are pregnant or for those who are under the age of 18 or over the age of 70. In addition, the Enterra system may be affected by or adversely affect cardiac pacemakers, cardioverters/defibrillators, external defibrillators, magnetic resonance imaging (MRI), ultrasonic equipment, electrocautery, radiation therapy, and theft detectors. Diathermy (e.g., shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy) is contraindicated since for patients with a neurostimulation system. Diathermy's energy can be transferred through the implanted system (or any of the separate implanted components), which can cause tissue damage and can result in severe injury or death. Diathermy can damage parts of the neurostimulation system.

Several radiopaque markers have been approved by the FDA for colonic transit testing. See the following Web site for more information (use product code FFX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed April 19, 2014.

Defecography is a procedure and, therefore, is not subject to FDA approval or clearance. 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 web page: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed April 19, 2014.

Additional Products
Polygram Net Electrogastrography Application Soft and Zinetics AMC

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for gastric electrical stimulation therapy. Local Coverage Determinations (LCDs) do not exist at this time, however, Local Articles do exist. Compliance with these policies is required where applicable. See the Local Articles for Enterra® Gastric Electrical Stimulation System Humanitarian Device Exemption R3 and Enterra® GASTRIC Electrical STIMULATION System HDE.

Medicare doses not have a National Coverage Determination (NCD) for rectal sensation, tone, and compliance testing. Local Coverage Determinations (LCDs) or Local Articles do not exist at this time.

Medicare does not have a National Coverage Determination (NCD) for anorectal manometry. Local Coverage Determinations (LCDs) exist and compliance with these policies is required where applicable. See the LCDs: Biofeedback, Anorectal Manometry, Anal Electromyography, and Biofeedback Training for Perineal Muscles and Anorectal or Urethral Sphincters and Anorectal Manometry and EMG of the Urinary and Anal Sphincters.

Medicare doses not have a National Coverage Determination (NCD) for cutaneous, mucous or serosal electrogastrography or electroenterography. CPT codes for these procedures (91132, 91133 and 91112) are listed in the Local Coverage Determinations (LCDs) for Non-Covered Services. Compliance with these policies is required where applicable.

Medicare doses not have a National Coverage Determination (NCD) for colonic manometry. Local Coverage Determinations (LCDs) or Local Articles do not exist at this time.

Medicare doses not have a National Coverage Determination (NCD) for magnetic resonance defecography or defecography in general. However, there is an NCD for Magnetic Resonance Imaging (220.2). Local Coverage Determinations (LCDs) or Local Articles for magnetic resonance defecography or defecography do not exist at this time. Accessed April 19, 2014.

REFERENCES

Abell TL, Van Cutsem E, Abrahamsson H, et al. Gastric electrical stimulation in intractable symptomatic gastroparesis. Digestion. 2002;66(4):204-212.

Abell T, Lou J, Tabbaa M, Batista O, et al. Gastric electrical stimulation for gastroparesis improves nutritional parameters at short, intermediate, and long-term follow-up. JPEN J Parenter Enteral Nutr. 2003a Jul-Aug;27(4):277-81.

Abell T, McCallum R, Hocking M, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterology. 2003b Aug;125(2):421-8.

American Gastroenterological Association (AGA) Medical Position Statement on Anorectal Testing Techniques. 1999. Available at: http://www.gastrojournal.org/article/S0016-5085(99)70194-0/fulltext Accessed April 19, 2014.

American Gastroenterological Association (AGA). AGA Technical Review on Anorectal Testing Techniques. 1999. Available at: http://download.journals.elsevierhealth.com/pdfs/journals/0016-5085/PIIS0016508599701952.pdf Accessed April 19, 2014.

American Gastroenterological Association (AGA), Bharucha AE, Dorn SD, Lembo A, et al. American Gastroenterological Association Medical Position Statement on Constipation. Gastroenterology. 2013 Jan;144(1):211-7.

Anand C, Al-Juburi A, Familoni B, et al. Gastric electrical stimulation is safe and effective: a long-term study in patients with drug-refractory gastroparesis in three regional centers. Digestion. 2007;75(2-3):83-89.

Bentur L, Hino B, Shamir R, et al. Impaired gastric myolectrical activity in patients with cystic fibrosis. J Cyst Fibros. 2006 Aug;5(3):187-91.

Bharucha AE, Pemberton JH, Locke GR 3rd. American Gastroenterological Association technical review on constipation. Gastroenterology. 2013 Jan;144(1):218-38.

Camilleri M, Bharucha AE, di Lorenzo C, et al. American Neurogastroenterology and Motility Society consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice. *Neurogastroenterol Motil*. 2008;20(12):1269-1282.

Camilleri M, Parkman HP, Shafi MA, et at. American College of Gastroenterology. Clinical guideline: management of gastroparesis. Am J Gastroenterol. 2013 Jan;108(1):18-37.

Cappabianca S, Reginelli A, Iacobellis F, et al. Dynamic MRI defecography vs. entero-colpo-cysto-defecography in the evaluation of midline pelvic floor hernias in female pelvic floor disorders. Int J Colorectal Dis. 2011 Sep;26(9):1191-6.

Chen CL, Lin HH, Chen SY, et a.. Utility of electrogastrography in differentiating Parkinson's disease with or without gastrointestinal symptoms: a prospective controlled study. Digestion. 2005;71(3):187-91.

Chen JD, Lin Z, Pan J, et al. Abnormal gastric myoelectrical activity and delayed gastric emptying in patients with symptoms suggestive of gastroparesis. Dig Dis Sci. 1996;41(8):1538-1545.

Chu H, Lin Z, Zhong L, et al. Treatment of high-frequency gastric electrical stimulation for gastroparesis. J Gastroenterol Hepatol. 2012 Jun;27(6):1017-26.

Di Lorenzo C, Flores AF, Reddy SN, Hyman PE. Use of colonic manometry to differentiate causes of intractable constipation in children. J Pediatr. 1992 May;120(5):690-5.

Di Lorenzo C, Solzi GF, Flores AF, et al. Colonic motility after surgery for Hirschsprung's disease. Am J Gastroenterol. 2000 Jul;95(7):1759-64.

Dobben AC, Wiersma TG, Janssen LW, et al., Stoker J. Prospective assessment of interobserver agreement for defecography in fecal incontinence. AJR Am J Roentgenol. 2005 Nov;185(5):1166-72.

ECRI Institute. Hotline Response. Gastric Electrical Stimulation for Treating Gastroparesis. December 2011.

Foti PV, Farina R, Riva G, et al. Pelvic floor imaging: comparison between magnetic resonance imaging and conventional defecography in studying outlet obstruction syndrome. Radiol Med. 2013 Feb;118(1):23-39.

Frasko R, Maruna P, Gurlich R, et al. Transcutaneous electrogastrography in patients with ileus. Relations to interleukin-1beta, interleukin-6, procalcitonin and C-reactive protein. Eur Surg Res. 2008;41(2):197-202.

Giorgio V, Borrelli O, Smith VV, et al. High-resolution colonic manometry accurately predicts colonic neuromuscular pathological phenotype in pediatric slow transit constipation. Neurogastroenterol Motil. 2013 Jan;25(1):70-8.e8-9.

Groenendijk AG, van der Hulst VP, Birnie E, et al. Correlation between posterior vaginal wall defects assessed by clinical examination and by defecography. Int Urogynecol J Pelvic Floor Dysfunct. 2008 Sep;19(9):1291-7.

Hayes, Inc. Medical Technology Directory. Gastric Electrical Stimulation for Gastroparesis. April 2012.

Liang H, Lin Z, McCallum RW. Application of combined genetic algorithms with cascade correlation to diagnosis of delayed gastric emptying from electrogastrograms. Med Eng Phys.

2000;22(3):229-234.

Lin Z, Sarosiek I, Forster J, et al. Association of the status of interstitial cells of Cajal and electrogastrogram parameters, gastric emptying and symptoms in patients with gastroparesis. Neurogastroenterol Motil. 2010 Jan;22(1):56-61, e10.

Martin MJ, Steele SR, Mullenix PS, et al. A pilot study using total colonic manometry in the surgical evaluation of pediatric functional colonic obstruction. J Pediatr Surg 2004; 39: 352–9.

McCallum RW, Abell T, Hocking M, et al. WAVESS Study Group. Worldwide AntiVomiting Electrical Stimulation Study (WAVESS) Group. 2002.

McCallum RW, Lin Z, Forster J, et al. Gastric electrical stimulation improves outcomes of patients with gastroparesis for up to 10 years. Clin Gastroenterol Hepatol. 2011 Apr;9(4):314-319.e1.

McCallum RW, Snape W, Brody F, et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. Clin Gastroenterol Hepatol. 2010 Nov;8(11):947-54.

Muñoz Yagüe T, Alvarez Sánchez V, Ibáñez Pinto A, et al. Clinical, anorectal manometry and surface electromyography in the study of patients with fecal incontinence. Rev Esp Enferm Dig. 2003 Sep;95(9):635-9, 629-34.

Musunuru S, Beverstein G, Gould J. Preoperative predictors of significant symptomatic response after 1 year of gastric electrical stimulation for gastroparesis. World J Surg. 2010 Aug;34(8):1853-8.

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. Constipation Guideline Committee of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. Evaluation and treatment of constipation in infants and children: recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. J Pediatr Gastroenterol Nutr. 2006 Sep;43(3):e1-13.

Noviello C, Cobellis G, Papparella A, et al. Role of anorectal manometry in children with severe constipation. Colorectal Dis. 2009 Jun;11(5):480-4.

O'Grady G, Angeli TR, Du P, et al. Abnormal initiation and conduction of slow-wave activity in gastroparesis, defined by high-resolution electrical mapping. Gastroenterology. 2012 Sep;143(3):589-98.e1-3.

O'Grady G, Egbuji JU, Du P, et al. High-frequency gastric electrical stimulation for the treatment of gastroparesis: a meta-analysis. World J Surg. 2009 Aug;33(8):1693-701.

Otto SD, Oesterheld A, Ritz JP, et al. Rectal anatomy after rectopexy: cinedefecography versus MR-defecography. J Surg Res. 2011 Jan;165(1):52-8.

Parkman HP, Hasler WL, Fisher RS; American Gastroenterological Association. American Gastroenterological Association medical position statement: diagnosis and treatment of gastroparesis. Gastroenterology. 2004 Nov;127(5):1589-91.

Parkman HP, Hasler WL, Fisher RS; American Gastroenterological Association. American Gastroenterological Association technical review on the diagnosis and treatment of gastroparesis. Gastroenterology. 2004 Nov;127(5):1592-622.

Pensabene L, Youssef NN, Griffiths JM, et al. Colonic manometry in children with defecatory disorders. role in diagnosis and management. Am J Gastroenterol. 2003 May;98(5):1052-7.

Pucciani F, Ringressi MN. Obstructed defecation: the role of anorectal manometry. Tech Coloproctol. 2012 Feb;16(1):67-72.

Rao SS; American College of Gastroenterology Practice Parameters Committee. Diagnosis and management of fecal incontinence. American College of Gastroenterology Practice Parameters Committee. Am J Gastroenterol. 2004 Aug;99(8):1585-604.

Rao SS, Ozturk R, Laine L. Clinical utility of diagnostic tests for constipation in adults: a systematic review. Am J Gastroenterol. 2005 Jul;100(7):1605-15.

Rao SS, Sadeghi P, Beaty J, Kavlock R. Ambulatory 24-hour colonic manometry in slow-transit constipation. Am J Gastroenterol. 2004 Dec;99(12):2405-16.

Rao SS, Singh S, Mudipalli R. Day-to-day reproducibility of prolonged ambulatory colonic manometry in healthy subjects. Neurogastroenterol Motil. 2010a Jun;22(6):640-e178.

Reiner CS, Tutuian R, Solopova AE, et al. MR defecography in patients with dyssynergic defecation: spectrum of imaging findings and diagnostic value. Br J Radiol. 2011 Feb;84(998):136-44.

Savoye-Collet C, Savoye G, Koning E, et al. Defecographic disorders in anal incontinent women: relation to symptoms and anal endosonographic patterns. Scand J Gastroenterol. 2005 Feb;40(2):141-6.

Sha W, Pasricha PJ, Chen JD. Correlations among electrogastrogram, gastric dysmotility, and duodenal dysmotility in patients with functional dyspepsia. J Clin Gastroenterol. 2009 Sep;43(8):716-22

Singh S, Heady S, Coss-Adame E, et al. Clinical utility of colonic manometry in slow transit constipation. Neurogastroenterol Motil. 2013 Feb 6.

Sood MR, Mousa H, Tipnis N, et al. Interobserver variability in the interpretation of colon manometry studies in children. J Pediatr Gastroenterol Nutr. 2012 Nov;55(5):548-51.

Takada M, Yamamoto T, Takada H, et al. Analysis of electrogastrography in gastrectomized subjects. Nippon Eiseigaku Zasshi. 2011 Jan;66(1):64-70.

Ternent CA, Bastawrous AL, Morin NA, et al., Standards Practice Task Force of The American Society of Colon and Rectal Surgeons. Practice parameters for the evaluation and management of constipation. Dis Colon Rectum 2007 Dec;50(12):2013-22.

Tipnis NA, El-Chammas KI, Rudolph CD, et al. Do Oro-anal Transit Markers Predict Which Children Would Benefit From Colonic Manometry Studies? J Pediatr Gastroenterol Nutr. 2012 Feb;54(2):258-62.

Tjandra JJ, Dykes SL, Kumar RR, et al., Standards Practice Task Force of the American Society of Colon and Rectal Surgeons. Practice parameters for the treatment of fecal incontinence. Dis Colon Rectum 2007 Oct;50(10):1497-507.

Tomita R, Igarashi S, Fujisaki S, et al. Significance of defecography in the diagnosis and evaluation of male patients with defecation disorders. Hepatogastroenterology. 2010 Mar-Apr;57(98):220-3.

Van den Berg MM, Hogan M, Caniano DA, et al. Colonic manometry as predictor of cecostomy success in children with defecation disorders. J Pediatr Surg 2006; 41: 730–6.

Varma M, Rafferty J, Buie WD; Standards Practice Task Force of American Society of Colon and Rectal Surgeons. Practice parameters for the management of rectal prolapse. Dis Colon Rectum. 2011 Nov;54(11):1339-46.

Villarreal J, Sood M, Zangen T, et al. Colonic diversion for intractable constipation in children: colonic manometry helps guide clinical decisions. J Pediatr Gastroenterol Nutr. 2001 Nov;33(5):588-91.

Vitton V, Vignally P, Barthet M, et al. Dynamic anal endosonography and MRI defecography in diagnosis of pelvic floor disorders: comparison with conventional defecography. Dis Colon Rectum. 2011 Nov;54(11):1398-404.

Wiklendt L, Mohammed SD, Scott SM, et al. Classification of normal and abnormal colonic motility based on cross-correlations of pancolonic manometry data. Neurogastroenterol Motil. 2013 Mar;25(3):e215-23.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
08/01/2014	• Reorganized policy content • Added benefit considerations language for *Essential Health Benefits for Individual and Small Group* plans to indicate: o For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") o Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans o The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Updated coverage rationale: o Reformatted and relocated information pertaining to medical necessity review; added language to indicate if service is "medically necessary" or "not medically necessary" to applicable proven/unproven statement • Archived previous policy version 2014T0415L