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Gastrointestinal (GI) Motility Measurement

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
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Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

Colon motility (manometric) testing **may be considered medically necessary** to guide decision-making for surgery in children (i.e., < 18 years of age) with refractory colonic motility/defecatory disorders.

Colon motility (manometric) testing **is considered experimental, investigational and/or unproven** for all other indications.

Measurement of gastrointestinal (GI) transit times, including gastric emptying and colonic transit times using an ingestible pH and pressure capsule (e.g., SmartPill® GI Monitoring System), or electrogastrography (EGG) (e.g., Gastric Alimetry® System, G-Tech GutTracker™ wireless patch system) is **considered experimental, investigational and/or unproven** including,

but not limited to, for evaluation of suspected gastroparesis, constipation, or other GI motility disorders.

Policy Guidelines

None.

Description

Gastroparesis and Constipation
Gastroparesis is a chronic disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal (GI) tract disorders. It can be caused by many conditions; most commonly it is idiopathic, diabetic, or postsurgical.

Constipation is a chronic disorder involving infrequent bowel movements, a sensation of obstruction, and incomplete evacuation. Many medical conditions can cause constipation, such as mechanical obstruction, metabolic conditions, myopathies, and neuropathies. Diagnostic testing for constipation can aid in distinguishing between 2 categories of disorders, slow-transit constipation, and pelvic floor dysfunction.

Diagnosis
Gastric emptying scintigraphy is considered the reference standard for diagnosing gastroparesis. The patient ingests a radionuclide-labeled standard meal and subsequent imaging is performed at 0, 1, 2, and 4 hours postprandially, to measure how much of the meal has passed beyond the stomach. A typical threshold to indicate abnormal gastric emptying is more than 10% of the meal remaining at 4 hours after ingestion.

Standard tests used in the evaluation of constipation include ingestion of radiopaque markers and colonic transit scintigraphy. In the radiopaque markers test, small markers are ingested over 1 or several days, and abdominal radiographs are performed at 4 and/or 7 days. The number of remaining markers correlates with the colonic transit time. In colonic transit scintigraphy, a radio-labeled meal is ingested, followed by scintigraphic imaging at several time intervals. The location of the scintigraphic signals correlates with colonic transit times.

A number of other tests have been investigated for evaluating disorders of GI motility.

Colon Motility (Manometric) Testing
Colon motility testing or colonic manometry is the recording of intraluminal pressures from within the large bowel by means of a manometric catheter, which 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.

Ingestible pH and Pressure Capsule
An ingestible pH and pressure-sensing capsule (SmartPill® GI Monitoring System) measures pH, pressure, and temperature changes to signify the passage of the capsule through portions of the GI tract. It is proposed as a means of evaluating gastric emptying for diagnosis of gastroparesis, and colonic transit times for the diagnosis of slow-transit constipation.

Electrogastrography
Electrogastrography describes the recording and interpretation of electrical activity of the stomach, typically from the skin surface. The usual practice is to record several cutaneous electrical signals from various standardized positions on the abdominal wall and to select the one with the highest amplitude for further analysis. Nonetheless, the recorded signal is relatively weak and difficult to distinguish from the surrounding background "noise" related to unwanted signals, such as cardiac, respiratory, duodenal, and colonic electrical activity. For this reason, direct visual analysis of the electrogastrography (EGG) signals is problematic. Various methods of filtering out background noise and automated analysis have been developed; running spectral analysis is most common. The EGG is usually evaluated in terms of changes in the EGG amplitude and frequency.

Regulatory Status
In 2006, an ingestible capsule (SmartPill® GI Monitoring System; Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process, for evaluation of delayed gastric emptying. Gastric emptying is signaled when the pH monitor in the capsule indicates a change in pH from the acidic environment of the stomach to the alkaline environment of the small intestine. For example, an increase of 2 or more pH units usually indicates gastric emptying, and a subsequent decrease of 1 or more pH units usually indicates a passage to the ileocecal junction. While SmartPill® does not measure 50% emptying time, it can be correlated with scintigraphically measured 50% emptying time. The capsule also measures pressure and temperature during its transit through the entire gastrointestinal tract, allowing calculations of total gastrointestinal tract transit time. In 2009, the FDA expanded the use of the SmartPill® to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow-and normal-transit constipation. When colonic transit time cannot be determined, small and large bowel transit times combined can be used instead. The SmartPill® is not for use in pediatric patients. FDA product code: NYV.

In June 2022, the FDA granted original 510(k) marketing clearance to the Gastric Alimetry® System. Defined as an electrogastrography device, the indications for use were described as follows: "The Gastric Alimetry System is intended to record, store, view and process gastric myoelectrical activity as an aid in the diagnosis of various gastric disorders." (1) An array with recording electrodes on an adhesive patch is used for recording the myoelectrical data from the skin surface, which allows the device to acquire and digitize the myoelectrical data and movement artifacts. FDA product code: MYE.

In January 2022, the FDA granted 510(k) marketing clearance to the G-Tech Wireless Patch System, to serve as a tool that provides GI myoelectrical activity measurements using cutaneous electrodes at the abdominal skin surface to aid in the diagnosis and evaluation of GI disorders. (2) FDA product code: MYE.

Rationale

Medical policies assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

Colonic Motility Testing or Colonic Manometry
In 2010, Dinning et al. critically examined the role of colonic manometry in clinical practice, and how manometric assessment may aid diagnosis, classification and guide therapeutic intervention in the constipated individual, considering both adult and pediatric patients. (3) In adults, very few interventional studies have been based upon evidence gained from colonic manometric investigation. In children, colonic manometry studies are far more likely to guide treatment options. Because a normal frequency of high-amplitude propagating sequences (HAPS) has been identified in children with slow-transit constipation (contradicting most reported findings in adults), childhood constipation may represent a different entity.

Pensabene et al. (2003) conducted a retrospective review of medical records for 145 children to evaluate the impact of colonic manometry in clarifying pathophysiology of childhood defecatory disorders and evaluated its impact on management. (4) Treatment changes were recommended in 93% of patients after colonic manometry. 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.

van den Berg et al. (2006) sought to define the predictive value of colonic manometry and contrast enema before cecostomy placement in children with defecation disorders. (5) Medical records, contrast enema, and colonic manometry studies were reviewed for 32 children with defecation disorders who underwent cecostomy placement between 1999 and 2004. Diagnoses included idiopathic constipation (n = 13), Hirschsprung's disease (n = 2), cerebral palsy (n = 1), imperforate anus (n = 6), spinal abnormality (n = 6), and anal with spinal abnormality (n = 4). Contrast enemas were evaluated for the presence of anatomic abnormalities and the degree of colonic dilatation. Colonic manometry was considered normal when high amplitude

propagating contractions (HAPC) occurred from proximal to distal colon. Clinical success was defined as normal defecation frequency with no or occasional fecal incontinence.
Colonic manometry was done on 32 and contrast enema on 24 patients before cecostomy. At follow-up, 25 patients (78%) fulfilled the success criteria. Absence of HAPC throughout the colon was related to unsuccessful outcome (P = .03). Colonic response with normal HAPC after bisacodyl administration was predictive of success (P = .03). Presence of colonic dilatation was not associated with colonic dysmotility. The authors concluded that colonic manometry is helpful in predicting the outcome after cecostomy. Patients with generalized colonic dysmotility are less likely to benefit from use of antegrade enemas via cecostomy. Normal colonic response to bisacodyl predicts favorable outcome.

Mugie et al. (2013) compared the diagnostic yield and tolerability of colonic manometry and colonic scintigraphy in children with severe constipation. (6) Twenty-six children (mean age 11.4 years, 77% boys) who had received colonic manometry and colonic scintigraphy as part of a colonic motility evaluation were included. Manometry was performed as per department protocol. After swallowing a methacrylate-coated capsule containing indium-111, images were taken at 4, 24, and 48 hours, and geometric centers were calculated. Results of both tests were categorized in 3 groups: normal, abnormal function in the distal part of the colon, and colonic inertia. Cohen κ was used for the level of agreement. Patients and parents completed a questionnaire regarding their experience. Colonic scintigraphy showed normal transit time in 20%, delay in the distal colon in 48%, and colonic inertia in 32% of patients. Colonic manometry was normal in 40%, abnormal in the distal colon in 40%, and colonic inertia was diagnosed in 20%. The κ score was 0.34. All 5 patients with colonic inertia during manometry had a similar result by scintigraphy. Eighty-eight percent of patients preferred scintigraphy over manometry and 28% of parents preferred colonic manometry over scintigraphy. Authors concluded that colonic manometry and colonic scintigraphy have a fair agreement regarding the categorization of constipation.

Section Summary: Colonic Motility Testing or Colonic Manometry
The evidence regarding the effectiveness of colon manometry or colonic motility testing consists of small sample size studies. However, the data does support that in refractory patients, colonic manometry may be useful in providing additional information useful in guiding therapy in children.

Ingestible pH and Pressure Capsules
Clinical Context and Test Purpose
The purpose of diagnostic testing with an ingestible pH and pressure capsule in individuals who have suspected disorders of gastric emptying or have suspected slow-transit constipation is to inform a decision whether to proceed to appropriate treatment.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals with suspected disorders of gastric emptying or with suspected slow-transit constipation.

Interventions
The test being considered is diagnostic testing with an ingestible pH and pressure capsule.

Comparators
The following tests are currently being used to diagnose suspected disorders of gastric emptying or slow-transit constipation: scintigraphy and radiopaque markers.

Although scintigraphy is considered the reference standard for evaluating gastric emptying, several issues complicate its use as a reference test. Until recently, there has been a lack of test standardization. (7) Significant day-to-day variability in the rate of gastric emptying has also been noted. (8)

Due to a lack of standardization and small sample sizes referenced in published studies, the capability of the gastric emptying test to discriminate between healthy individuals and those with known gastroparesis is uncertain. In a study by Tougas et al. (2000), 123 healthy subjects were assessed to determine the normal period required for nearly complete evacuation of a standardized meal from the stomach. (9) The authors suggested that the threshold of normality for gastric retention at 4 hours is 10% meal retention. The cutoff point was set to include 95% of normal persons. However, it appears to be unknown if this same threshold adequately identifies persons who would otherwise be classified as having gastroparesis and who are candidates or responders to treatment.

Outcomes
The general outcomes of interest are reductions in gastrointestinal discomfort and pain and improvements in quality of life. Comparisons between the ingestible capsule and scintigraphy could be done concurrently.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this medical policy and alternative sources exist. This medical policy focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Gastric Emptying
A few published studies have evaluated the ingestible capsule in relation to another diagnostic measure of gastric emptying. A systematic review of 12 studies on the ingestible capsule was conducted by Stein et al. (2013) for the Agency for Healthcare Research and Quality (AHRQ; see

Table 1). (10) Studies that included only healthy participants were excluded from the review; instead, AHRQ looked for studies with comparison groups consisting of healthy, asymptomatic (i.e., without symptoms of gastroparesis or constipation) participants as controls. Among these studies, 5 were only available as meeting presentations, and the overall strength of evidence favoring the ingestible capsule was low. Diagnostic accuracy with the ingestible capsule was considered comparable to gastric scintigraphy in 7 studies, 3 of which were in abstracts only. There was a moderate correlation between the ingestible capsule and gastric emptying scintigraphy on transit data and device agreement in 5 studies.

Table 1. Characteristics and Results of Systematic Reviews

Study	Studies Included	Study Populations Included	Study Designs Included	Study Reference Standards Included	Sens, %	Spec, %	SOE
Stein et al. (2013) (10) (AHRQ)	12	Patients with gastroparesis or constipation or healthy controls	7 studies were prospective, 5 of 7 were multicenter	Scintigraphy	59-86	64-81	Low

AHRQ: Agency for Healthcare Research and Quality; Sens: sensitivity; SOE: strength of evidence; Spec: specificity.

A study by Green et al. (2013) assessed SmartPill and gastric emptying scintigraphy in 22 pediatric patients with severe upper gastrointestinal (GI) symptoms. (11) Of 20 evaluable patients who had both tests, 9 patients had delayed gastric emptying. Patients also underwent antroduodenal manometry to detect motor abnormalities. SmartPill identified motor abnormalities in 17 patients, compared with 10 detected by antroduodenal manometry. However, because there does not appear to be a reference standard for motor abnormalities, it cannot be determined whether SmartPill is more sensitive or whether it has a higher false-positive rate for detection of motor abnormalities.

Lee et al. (2019) reported on delayed gastric emptying time in 167 individuals with gastroparesis who were assessed simultaneously by wireless motility capsule (WMC) and gastric emptying scintigraphy. (12) Delayed gastric emptying by WMC was defined as more than 5 hours before passage of the capsule into the duodenum and delayed emptying by gastric emptying scintigraphy was defined as at least 10% meal retention at 4 hours. Delayed gastric emptying time by WMC occurred in 53 individuals (34.6%) and delayed gastric emptying by gastric emptying scintigraphy occurred in 39 individuals (24.5%). There was an overall device agreement between WMC and gastric emptying scintigraphy of 75.7%. Severely delayed gastric emptying was identified in 21 individuals (13.8%) by WMC and 11 individuals (7%) with gastric emptying scintigraphy. Agreement between WMC and gastric emptying scintigraphy for severe delayed gastric emptying was 38%. Significantly higher proportions of individuals with delayed and severely delayed emptying were identified by WMC.

Sagnes et al. (2019) reported on 72 individuals with diabetes mellitus and suspected gastroparesis. (13) The correlation between WMC and 4-hour gastric emptying scintigraphy was r=0.74 (p<0.001). At a cutoff of 300 minutes for gastric emptying time with WMC, the sensitivity compared with gastric emptying scintigraphy was 0.92 (95% confidence interval [CI], 0.74 to 0.99) and the specificity was 0.73 (95% CI, 0.57 to 0.86). The investigators found that the optimal cutoff for WMC was 385 minutes, for which the sensitivity was 92% (95% CI, 0.74 to 0.99) and the specificity was 0.83 (95% CI, 0.68 to 0.93). Although the Lee and Sagnes studies included the population of interest, the impact of diagnosis by WMC and gastric emptying scintigraphy on patient management or health outcomes was not addressed.

Subsection Summary: Clinical Validity for Gastric Emptying

The data present several shortcomings on the use of the SmartPill in diagnosing gastroparesis; as a result, the diagnostic accuracy is not well defined. The current reference test (gastric emptying scintigraphy) is an imperfect criterion standard, and this creates difficulties in defining the sensitivity and specificity of SmartPill. Studies included healthy asymptomatic subjects as part of a control group. Although there was a moderate correlation between SmartPill gastric emptying time and scintigraphy, scintigraphy itself has limited reliability. Although the areas under the curve between SmartPill and scintigraphy are similar, the modest correlation between the 2 tests indicates that there are often discordant results.

Constipation

Few studies have evaluated the use of SmartPill for assessing colonic transit times. In the systematic review by Stein et al. (2013) conducted for AHRQ, the strength of evidence in available studies on the ingestible capsule was found to be low overall. (10) No studies were identified that compared the SmartPill to colonic scintigraphy. Accuracy of the ingestible capsule in diagnosing slow-transit constipation was similar to tests using radiopaque markers. A moderate correlation between colonic transit times with the ingestible capsule and tests with radiopaque markers was shown in 5 studies (*r* range, 0.69-0.71).

Subsection Summary: Clinical Validity for Constipation

Although the studies included in the AHRQ systematic review showed moderate correlations between SmartPill and other methods for assessing colonic transit times, they should be interpreted cautiously. The diagnostic capability of SmartPill for detecting slow-transit constipation is unknown.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the

preferred evidence would be from randomized controlled trials. No randomized controlled trials were identified.

Gastric Emptying and Constipation
The 2013 AHRQ review found that there was a lack of evidence on the clinical utility of testing with the ingestible capsule. (10) The review found 3 studies, including 1 abstract, on management changes following use of the SmartPill. Kuo et al. (2011) (14) and Rao et al. (2011) (15) reported that wireless motility capsule testing resulted in a new diagnosis in about 50% of patients. Due to the limited data, AHRQ reviewers considered the evidence insufficient to determine the impact of testing results of the ingestible capsule on treatment and management decisions.

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. Because the clinical validity of an ingestible pH and pressure capsule has not been established, a chain of evidence supporting the clinical utility of the device cannot be constructed.

Subsection Summary: Clinically Useful
Evidence on the clinical utility of a wireless pressure capsule is very limited, consisting of 3 retrospective analyses describing outcomes of patients undergoing testing with SmartPill. These studies lacked control subjects diagnosed without the test or with alternative tests. This evidence is insufficient to determine the clinical utility of SmartPill for either indication; higher quality studies are still needed to measure the impact of SmartPill on patient management and improved health outcomes.

UpToDate
In patients with suspected gastroparesis and no evidence of a mechanical obstruction, an assessment of gastric motility is necessary to establish the diagnosis. According to a 2024 UpToDate article (16), "The most cost-effective, simple, and widely available technique to confirm the presence of delayed gastric emptying of solids is scintigraphy."

Electrogastrography
Body Surface Gastric Mapping
Schamberg et al. (2023) directly compared traditional electrogastrography (EGG) and newer EGG technology of body surface gastric mapping (BSGM) combined with validated symptom profiling to define performance differences in spectral analysis. (17) Comparisons between Gastric Alimetry (GA) BSGM and traditional EGG were conducted by protocolized retrospective evaluation of 178 subjects [110 controls; 68 nausea and vomiting (NVS) and/or type 1 diabetes (T1D)]. Comparisons followed standard methodologies for each test (pre-processing, post-processing, analysis), with statistical evaluations for group-level differences, symptom correlations, and patient-level classifications. BSGM showed substantially tighter frequency ranges vs traditional EGG in controls. Both tests detected rhythm instability in NVS, but EGG showed opposite frequency effects in T1D. BSGM showed an 8× increase in the number of significant correlations with symptoms. BSGM accuracy for patient-level classification was 0.78

for patients vs controls and 0.96 as compared to blinded consensus panel; EGG accuracy was 0.54 and 0.43. Traditional EGG detected group-level differences in patients but lacked symptom correlations and showed poor accuracy for patient-level classification. BSGM demonstrated substantial performance improvements across all domains.

The authors stated that there are several factors to be considered when interpreting these findings, especially as they relate to the existing EGG literature. First, EGG analysis was performed using an automated artifact detection algorithm. It was possible that manual approaches could have improved results, although the automated system used is well-validated against expert manual marking. Second, proprietary signal processing steps could be used in commercial EGG devices, which are not disclosed, and hence could not be implemented. Third, all tests were carried out using a standard 482 kCal meal, and other meals or water load tests have been applied in past EGG studies; however, these researchers selected this meal because their unpublished experience was that it generated a reliable electrophysiological response, whereas a water load did not. Fourth, these investigators only considered a single electrode configuration. This was based on EGG literature, although multi-channel EGG studies (e.g., up to 6 electrodes) have also been reported, and ultrasound (US) imaging has been used for antral localization. Presumably, the use of more channels would improve performance of the EGG pipeline, however, the authors' simpler experimental setup matched current commercially-available systems. Fifth, all stages of the EGG processing pipeline required decisions on specific approaches for which there may not be unanimous consensus in the literature. More importantly, for all of the above considerations, the selected approach has been implemented uniformly across the entire cohort based on published guidance, with the objective of minimizing any biasing effect that could artificially impair the ability of EGG outputs to differentiate patients from controls. Lastly, this trial focused only on spectral analyses of BSGM and EGG. While surface recordings are highly validated against invasive serosal recording, subtle abnormalities such as conduction blocks or stable ectopic pacemakers may not be captured by non-invasive techniques applying spectral metrics. Spatial analytics for non-invasive mapping are currently evolving, which could further improve the precision of BSGM and yield new phenotypes in the future. Moreover, use of gastric myoelectrical activity analyses for aiding in treatment and diagnosis of gastrointestinal disorders is supported by simultaneous evaluation of symptoms and complete patient medical history.

In a small retrospective case series, Varghese et al. (2023) aimed to assess the impact to diagnosis and health care utilization after the introduction of GA into clinical care. (18) Consecutive data of patients from 2 tertiary centers with chronic gastroduodenal symptoms (Rome-IV defined or motility disorder) having integrated care and GA testing were evaluated. Changes in diagnoses, interventions, and management were quantified. Pretest and posttest health care utilization was reported. A preliminary management framework was established through experiential learning. Fifty participants (45 women; median age 30 years; 18 with gastroparesis, 24 with chronic nausea and vomiting syndrome, and 6 with functional dyspepsia) underwent GA testing. One-third of patients had a spectral abnormality (18% dysrhythmic/ low amplitude). Of the remaining patients, 9 had symptoms correlating to gastric amplitude, while 19 had symptoms unrelated to gastric activity. Gastric Alimetry aided management decisions in

84%, including changes in invasive nutritional support in 9/50 cases (18%; predominantly de-escalation). Authors concluded that Gastric Alimetry aided diagnosis and management of patients with chronic gastroduodenal symptoms by enabling phenotype-informed care.

Both the Schamberg et al. (17) and Varghese et al. (18) studies were reviewed as part of a 2024 ECRI Clinical Evidence Assessment. (19) ECRI described the available evidence as "very-low-quality data", stating that the evidence from the studies was too limited in quantity and quality to enable conclusions about whether the Gastric Alimetry system influences patient management or improves patient outcomes.

Gastric emptying testing (GET) assesses gastric motility, however, is nonspecific and insensitive for neuromuscular disorders. Gastric Alimetry (GA) is a new medical device combining noninvasive gastric electrophysiological mapping and validated symptom profiling. A 2024 study from Wang et al. assessed patient-specific phenotyping using GA compared with GET. (20) Patients with chronic gastroduodenal symptoms underwent simultaneous GET and GA, comprising a 30-minute baseline, 99m TC-labelled egg meal, and 4-hour postprandial recording. Results were referenced to normative ranges. Symptoms were profiled in the validated GA App and phenotyped using rule-based criteria based on their relationships to the meal and gastric activity: (i) sensorimotor, (ii) continuous, and (iii) other. Seventy-five patients were assessed, 77% female. Motility abnormality detection rates were as follows: GET 22.7% (14 delayed, 3 rapid), GA spectral analysis 33.3% (14 low rhythm stability/low amplitude, 5 high amplitude, and 6 abnormal frequency), and combined yield 42.7%. In patients with normal spectral analysis, GA symptom phenotypes included sensorimotor 17% (where symptoms strongly paired with gastric amplitude, median r = 0.61), continuous 30%, and other 53%. GA phenotypes showed superior correlations with Gastroparesis Cardinal Symptom Index, Patient Assessment of Upper Gastrointestinal Symptom Severity Index, and anxiety scales, whereas Rome IV Criteria did not correlate with psychometric scores ($P > 0.05$). Delayed emptying was not predictive of specific GA phenotypes. Authors concluded that GA improves patient phenotyping in chronic gastroduodenal disorders in the presence and absence of motility abnormalities with increased correlation with symptoms and psychometrics compared with gastric emptying status and Rome IV criteria.

<u>Gastrointestinal Myoelectrical Activity Study</u>

The Wireless Patch System by G-Tech Medical (Mountain View, CA) measures gastrointestinal activity from the stomach through the colon continuously over multiple days. Per the manufacturer, this procedure would be used prior to more invasive exploratory diagnostic measures. Patches that measure myoelectric activity are applied to the skin. Data is continually uploaded to the cloud, where algorithms process the data. It has received 510(k) clearance from the U.S. Food and Drug Administration and is now commercially available. (2)

A prospective cohort study published in 2018 by Dua et al. included 75 patients following pancreaticoduodenectomy (PD) to determine if the Wireless Patch System by G-Tech can identify patients at risk for delayed gastric emptying (DGE). (21) After PD, battery-operated wireless patches (G-Tech Medical) that acquire gastrointestinal myoelectrical signals are placed

on the abdomen and transmit data by Bluetooth. Patients were divided into early and late groups by diet tolerance of 7 days [enhanced recovery after surgery (ERAS) goal]. Subgroup analysis was done of patients included after ERAS initiation. The early and late groups had 50 and 25 patients, respectively, with a length of stay (LOS) of 7 and 11 days ($P < 0.05$). Nasogastric insertion was required in 44% of the late group. Tolerance of food was noted by 6 versus 9 days in the early versus late group ($P < 0.05$) with higher cumulative gastric myoelectrical activity. Diminished gastric myoelectrical activity accurately identified delayed tolerance to regular diet in a logistical regression analysis [area under the curve (AUC): 0.81; 95% CI, 0.74–0.92]. The gastric myoelectrical activity also identified a delayed LOS status with an AUC of 0.75 (95% CI, 0.67– 0.88). This stomach signal continued to be predictive in 90% of the ERAS cohort, despite earlier oral intake. Measurement of gastric activity after PD can distinguish patients with shorter or longer times to diet. This noninvasive technology provides data to identify patients at risk for DGE and may guide the timing of oral intake by gastric "readiness."

The authors noted limitations in the study included the lack of prospective evidence that a surgical decision regarding feeding was made based on the patch recordings in vivo and around the concept of DGE itself. Gastric emptying studies have shown poor correlation with patient symptoms, and it may turn out that gastric myoelectrical activity is a better marker of physiology than gastric emptying. For this study, they did not have gastric emptying studies in conjunction with the myoelectrical measurements. It is possible that the concept of DGE and gastric dysfunction may evolve based on further utilization of this technology, demonstrating that such recordings truly reflect DGE using another method, such as gastric emptying scintigraphy. Nevertheless, their preliminary data could be generalizable to the larger population undergoing upper gastrointestinal surgery and could guide clinical decision-making in a larger prospective clinical trial using clinical end points, such as tolerance to feeding times and overall, LOS with actions suggested by the recordings along the clinical course. (21)

In an open prospective pilot study by Navalgund et al. in 2019, 18 patients who underwent open abdominal surgery had wireless patches placed on the abdomen following surgery. Colonic frequency peaks in the spectra were identified in select time intervals and the area under the curve of each peak times its duration was summed to calculate cumulative myoelectrical activity. Patients with early flatus had stronger early colonic activity than patients with late flatus. At 36 h post-surgery, a linear fit of time to flatus vs cumulative colonic myoelectrical activity predicted first flatus as much as 5 days (± 22 h) before occurrence. noninvasive measurement of colon activity after open abdominal surgery was feasible and predictive of time to first flatus. Interventions such as feeding can potentially be optimized based on this prediction, potentially improving outcomes, decreasing length of stay, and lowering costs. (22)

In November 2019, Taylor et al. published a proof-of-concept study on 3 pediatric patients who underwent abdominal surgery (ages 5 months, 4 years, 16 years). Multiple patches were placed on the older subjects, while the youngest had a single patch due to space limitations. Rhythmic signals of the stomach, small intestine, and colon could be identified in all three subjects. Patients showed gradual increase in myoelectric intestinal and colonic activity leading up to the

first recorded bowel movement. Measuring myoelectric intestinal activity continuously using a wireless patch system is feasible in a wide age range of pediatric patients. The increase in activity over time correlated well with the patients' return of bowel function. More studies are planned to determine if this technology can predict return of bowel function or differentiate between physiologic ileus and pathologic conditions. (23)

Lacy et al. (2024) conducted a novel pilot study to evaluate the efficacy and safety of a wireless patch system in patients with chronic nausea and vomiting. (24) Consecutive adult patients (age ≥ 18 years) referred for gastric emptying studies (GES) were eligible for study inclusion. Patients were excluded if they had prior foregut surgery; were taking opioids or other medications known to affect gastric emptying; had a HgbA1C > 10; or were recently hospitalized. Three wireless motility patches were applied to the skin prior to GES. Patients wore the patches for 6 days while recording meals, symptoms, and bowel movements using an iPhone app. Twenty-three consecutive adults (87% women; mean age = 43.9 years; mean BMI = 26.7 kg/m^2) were enrolled. A gastric histogram revealed three levels of gastric myoelectric activity: weak, moderate, and strong. Patients with delayed gastric emptying at 4 h had weak gastric myoelectrical activity. Patients with nausea and vomiting had strong intestinal activity. Those with functional dyspepsia (FD) had weak gastric and intestinal myoelectric activity, and a weak meal response in the stomach, intestine, and colon compared to those with nausea alone or vomiting alone. Patients with FD, and those with delayed gastric emptying, had unique gastrointestinal myoelectrical activity patterns. Reduced postprandial pan-intestinal myoelectric activity may explain the symptoms of FD in some patients. Recording gastrointestinal activity over a prolonged period in the outpatient setting has the potential to identify unique pathophysiologic patterns and meal-related activity that distinguishes patients with distinct gastric sensorimotor disease states.

UpToDate
In a 2024 UpToDate article, electrogastrography was described as “not widely performed” and its role in clinical practice as not being well established. (25)

Section Summary: Electrogastrography
While preliminary data for electrogastrography is promising, there is still a lack of quality evidence. Additional clinical validity studies using appropriate reference standards and larger sample sizes are needed to assess the diagnostic accuracy. Clinical utility studies are also needed to determine whether use of EEG to guide treatment and clinical decision making improves patient-relevant outcomes.

Practice Guidelines and Position Statements
Colonic Motility Testing or Colonic Manometry
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 (2017) (based on a systematic review of the evidence), 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 antegrade colonic enema (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. (26)

American Pediatric Surgical Association Board of Governors - Guidelines for the management of postoperative obstructive symptoms in children with Hirschsprung disease (2017)
The American Pediatric Surgical Association Board of Governors established a Hirschsprung Disease Interest Group. Group discussions, literature review and expert consensus were then used to summarize the current state of knowledge regarding causes, methods of diagnosis, and treatment approaches to children with obstructive symptoms following pull-through for Hirschsprung disease. Causes of obstructive symptoms post-pull-through include mechanical obstruction; persistent or acquired aganglionosis, hypoganglionosis, or transition zone pull-through; internal sphincter achalasia; disordered motility in the proximal intestine that contains ganglion cells; or functional megacolon caused by stool-holding behavior. An algorithm for the diagnosis and management of obstructive symptoms after a pull-through for Hirschsprung disease is presented. A stepwise, logical approach to the diagnosis and management of patients experiencing obstructive symptoms following pull-through for Hirschsprung disease can facilitate treatment. (27)

American Gastroenterological Association
An American Gastroenterological Association 2013 medical position statement includes a guideline on constipation that states colonic intraluminal testing (manometry, barostat) should be considered to document colonic motor dysfunction before colectomy (weak recommendation, moderate-quality evidence). (28) A weak recommendation implies that benefits, risks, and the burden of intervention are more closely balanced, or appreciable uncertainty exists regarding patient's values and preferences.

<u>Ingestible pH and Pressure Capsules</u>
American and European Neurogastroenterology and Motility Societies
The American and European Neurogastroenterology and Motility Societies issued a position paper on the evaluation gastrointestinal transit in 2011. (29) In it, the wireless motility capsule was recommended by consensus for assessing gastric emptying and small bowel, colonic, and whole-gut transit times in patients with suspected gastroparesis or gastrointestinal dysmotility in multiple regions. However, the position paper noted that the clinical utility of identifying delays in small bowel transit times is unknown.

American Gastroenterological Association
The 2022 American Gastroenterological Association (AGA) clinical practice guideline on management of medically refractory gastroparesis does not specifically have any best practice recommendations on use of wireless motility capsule, but does state, "Because the wireless motility capsule, an inanimate object, identifies the phase III activity front of the migrating

motor complex rather than overall gastric emptying, a meal-based test provides better physiological assessment of gastric emptying and is thus recommended as the first-line test of gastric emptying over the wireless motility capsule." (30)

Electrogastrography

American Gastroenterological Association

In 2004, a position statement on the diagnosis and treatment of gastroparesis from the American Gastroenterological Association reported that the guideline developers discussed, but did not recommend, the use of EGG to test for gastric myoelectrical activity. (8) In their 2022 Clinical Practice update (30), the AGA no longer any mentions or offer direction for the use of electrogastrography for the diagnosis of gastroparesis.

Summary of Evidence

For individuals with motility abnormalities, the evidence regarding the effectiveness of colon manometry or colonic motility testing consists of small sample size studies. However, the data does support that in refractory patients, colonic manometry may be useful in providing additional information useful in guiding therapy in children. Practice guidelines for the use of colon motility (manometric) testing to guide decision-making for surgery in children with refractory colonic motility/defecatory disorders supports this conclusion. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have suspected disorders of gastric emptying or suspected slow-transit constipation who receive diagnostic testing with an ingestible pH and pressure capsule, the evidence includes studies of test characteristics and case series of patients who have undergone the test. Relevant outcomes are test validity, other performance measures, symptoms, functional outcomes, and health status measures. The available studies have provided some comparative data on the SmartPill ingestible pH plus pressure-sensing capsule and other techniques for measuring gastric emptying. The evidence primarily consists of assessments of concordance with available tests. Because the available tests (e.g., gastric emptying scintigraphy) are imperfect criterion standards, it is not possible to determine the true sensitivity and specificity of SmartPill. The results of the concordance studies have revealed a moderate correlation with alternative tests but have provided only limited additional data on the true accuracy of the test in clinical care. Evaluation of cases with discordant results would be of particular value, and ideally, these studies should be linked to therapeutic decisions and to meaningful clinical outcomes. The evidence to date on clinical utility of testing is lacking, consisting of a small number of retrospective studies. It is not possible to determine whether there is net improvement in health outcomes using SmartPill vs standard diagnostic tests. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have suspected gastroparesis and other gastric or intestinal disorders, there is limited evidence evaluating the use of electrogastrography (EGG). While preliminary data is promising, there is still a lack of quality evidence. Additional clinical validity studies using appropriate reference standards and larger sample sizes are needed to assess the diagnostic

accuracy. Clinical utility studies are also needed to determine whether use of EEG to guide treatment and clinical decision making improves patient-relevant outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	91112, 91117, 91132, 91133, 91299, 0868T, 0779T, 0106U
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2025	Document became inactive.
02/01/2025	Document updated with literature review. The following change was made to Coverage: Added product example(s) to ingestible pH and pressure capsule, and to electrogastrography. Added references 1-3, 5, 6, 16-25, and 30; others removed.

07/15/2023	Reviewed. No changes.
01/01/2023	Document updated with literature review. Coverage unchanged. References 22, 30, and 31 were added and some removed.
08/01/2021	Reviewed. No changes.
12/01/2020	Document updated with literature review. The following change was made to the Coverage section: Colon motility (manometric) testing is now considered medically necessary to guide decision-making for surgery in children (i.e., < 18 years of age) with refractory colonic motility / defecatory disorders and experimental, investigational and/or unproven for all other indications. References 9, 14, 38, and 40-41 were added and some removed.
04/01/2019	Reviewed. No changes.
10/01/2018	Document updated with literature review. The following statement was added to Coverage: Colon motility (manometric) testing is considered experimental, investigational and/or unproven for all indications. References 3,12, and 40-46 were added.
04/15/2017	Reviewed. No changes.
04/15/2016	Document updated with literature review. Coverage unchanged.
07/01/2015	Reviewed. No changes.
07/01/2014	Document updated with literature review. Coverage unchanged.
09/15/2012	Document updated with literature review. Title changed from "Gastrointestinal (GI) Motility using the Smart Pill GI Monitoring System" to "Gastrointestinal (GI) Motility Measurement." The following changes were made: coverage was clarified, duodenal-jejunal manometry (DJM) was removed from coverage statement. The following statement was removed "This policy is no longer scheduled for routine literature review and update." CPT/HCPCS code(s) updated. Rationale revised.
12/15/2010	CPT codes updated.
12/01/2008	Revised/updated entire document
06/01/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
10/01/2006	Revised/updated entire document
01/01/2006	CPT/HCPCS code(s) updated
07/01/2004	Revised/updated entire document
04/01/1993	New medical document