Clinical Policy Bulletin: Gastrointestinal Function: Selected Tests

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Policy

Aetna considers electrogastrography or colonic motility studies (colonic manometry) experimental and investigational because their clinical utility has not been established.

Aetna considers high resolution esophageal pressure topography (HREPT) experimental and investigational because its clinical utility has not been established.

Aetna considers a wireless capsule for measuring gastric emptying parameters (SmartPill GI Monitoring System) experimental and investigational for the evaluation of gastric disorders (e.g., gastroparesis), intestinal motility disorders (e.g., chronic constipation), and all other indications because of inadequate published evidence of its diagnostic performance and clinical utility over conventional means of measuring gastric emptying.

Aetna considers radionuclide gastric emptying study medically necessary for the evaluation of gastrointestinal motility disorders, and gastroparesis.

Aetna considers magnetic resonance enterography medically necessary to evaluate and monitor Crohn's disease and other small bowel disorders.

See also CPB 0616 - Gastrointestinal Manometry.

Background

Cutaneous electrogastrography (EGG) is a non-invasive test that detects gastric arrhythmias by recording the frequency and regularity of gastric myoelectrical activity. It has been used to investigate the mechanisms of gastric motility and sensation in patients with gastric motility disorders or motion sickness. By means
of surface electrodes, EGG records gastric myoelectrical activity from the surface of the body. The cutaneous signals are low in amplitude, and thus must be markedly amplified. The resultant signals are heavily contaminated with noise, and visual analysis alone of EGG signals is inadequate. Consequently, EGG recordings require special methodology for acquisition, processing and analysis. 

There appears to be a close relationship between gastric myoelectrical activity and gastric motility. Although it has been reported that EGG satisfactorily reflects frequency of internal gastric myoelectrical activity, there is not acceptable correlation with gastric contractions or gastric emptying. Many attempts have been made to relate EGG “abnormalities” with clinical syndromes and diseases. Although abnormalities of the electrogastrogram have been described in a variety of disorders, their specificity and their prevalence in patients with functional gastrointestinal disorders have not been determined. Electrogastrography cannot determine the etiology of detected abnormalities because there are no specific EGG patterns to differentiate one epigastric condition from another. The clinical role of EGG remains to be established, and its proponents need to demonstrate that EGG results can affect therapeutic decisions.

Krusiec-Swidergol and Jonderko (2008) checked on reproducibility of parameters of a multi-channel electrogastrogram in adults after intake of typical, applied in EGG, test meals. Recordings of multi-channel electrogastrograms were accomplished in 4 blocks comprising 18 subjects (9 healthy volunteers and 9 patients with functional gastro-intestinal disorders) each. Every subject had 2 examinations taken 1 to 2 days apart, and a 3rd one was accomplished at least 2 weeks before or after the 2 other sessions. The registration involved a 30-min fasted and a 2-hr post-prandial period after one of the meal stimuli tested within a given block: 400 ml water, 400 g yoghurt (378 kcal), a scrambled eggs sandwich (370 kcal), a pancake (355 kcal). From among the parameters reflecting the propagation of the gastric slow waves, the average percentage of slow wave coupling (APSWC) exhibited a good (coefficient of variation for paired examinations CV(p) less than or equal to 10 %) to moderate (10 less than CV(p) less than or equal to 30 %) reproducibility. On the other hand, the reproducibility of the maximum dominant frequency difference and the spatial dominant power difference was found to be unsatisfactory. The reproducibility of the multi-channel EGG parameters did not differ between healthy volunteers and patients with functional gastrointestinal disorders. Gender or the kind of a test meal did not affect the reproducibility of the EGG parameters either. The medium-term reproducibility was not any worse than the short-term one. From among the parameters of a multi-channel EGG intended to quantify the propagation of slow waves, only the APSWC offers a reproducibility potentially good enough for clinical applications.

Colonic motility studies are used to assess the flow of intraluminal contents, the motions of the colonic wall that induce flow, and the control systems that integrate and regulate these processes. The approaches employed have consisted of manometric techniques to record colonic contractions, barostatic methods to measure colonic tone, and recordings of myoelectric signals from the colon that initiate and control muscular contractions. However, the study of colonic motility in a clinical setting proves to be difficult. Accurate positioning of the probes via colonoscopy requires pre-procedure cleansing of the colon, which raises the

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possibility of altered physiology. Recording of intra-luminal pressure, by means of manometric catheters inserted per rectum, requires prior bowel cleansing, which may modify colonic motility. In contrast to other segments of the gastro-intestinal tract, contents move through the colon in hours or days, instead of seconds to minutes; thus, prolonged observations are needed. Moreover, in contrast to the upper gastro-intestinal tract, in which reliable manometric recordings can be obtained, the larger diameter of the colon hinders the accurate detection of manometric events. Furthermore, interpretation of intra-luminal pressure measurements is complicated, because many contractions of the colonic wall do not occlude the lumen and therefore are detectable by manometry only if they cause significant pressure changes. And finally, all of these techniques, which continue to be used extensively in a research context, have not yet been standardized for routine clinical use.

Ghoshal et al (2007) stated that constipation is a common problem, which may be due to slow transit or fecal evacuation disorders. Though the screening test of colonic transit study using radio-opaque markers given at 0, 24 and 48 hours followed by abdominal X-ray at 72 hours is a good protocol in the West, it is not suitable for Indians who have a rapid gut transit. Nine patients with adult Hirschsprung disease, 11 with chronic intestinal pseudo-obstruction diagnosed using standard investigations and 11 healthy subjects were evaluated by colonic transit study using radio-opaque markers (SGmark), 20 each at O, 12 and 24 hours followed by an abdominal X-ray at 36 and 60 hours. The cut-off was determined by using receiver operating characteristic (ROC) curves, and sensitivity, specificity, positive and negative predictive values and diagnostic accuracy were determined. The total number of markers retained in the abdomen and those in the right segment at 36 hours in patients with Hirschsprung disease and chronic intestinal pseudo-obstruction was higher than that in healthy subjects though the number in the left and rectosigmoid segments were comparable. The abdominal X-ray at 60 hours, total number of markers and number in all segments were higher in patients with Hirschsprung disease and chronic intestinal pseudo-obstruction than in healthy subjects. The best cut-off by ROC curves at 36 and 60 hours was 30 and 14 markers, respectively. The sensitivity, specificity, positive and negative predictive values, diagnostic accuracy and area under the ROC curve at 36 hours were 90 %, 82 %, 90 %, 82 %, 87 % and 0.9, respectively; the corresponding values at 60 hours were 95 %, 100 %, 100 %, 92 %, 97 % and 0.99, respectively. The authors concluded that using the proposed protocol, the colonic transit study is able to distinguish patients with specific motility disorders causing constipation such as Hirschsprung disease and chronic intestinal pseudo-obstruction from healthy subjects with reasonable sensitivity and specificity, and shows that an abdominal X-ray at 60 hours is better than one at 36 hours. This was a small study reporting a moderate sensitivity and specificity of the colonic transit study; its findings need to be validated.

An American Gastroenterological Association guideline on nausea and vomiting (AGA, 2001) concluded that “the place of such tests of motor function as gastric emptying studies, electrogastrography, and manometry have not been defined, and the yield of such diagnostic studies has not been adequately compared with a therapeutic trial of an antiemetic and/or prokinetic agents.” An American Gastroenterological Association guideline on constipation (AGA, 2000) stated that colonic manometry “is not generally available and is not appropriate for most
patients, except in research settings." The consensus opinion of the American Motility Society Clinical GI Motility Testing Task Force on the performance and clinical utility of EGG (Parkman et al, 2003) stated that no therapies have convincingly demonstrated in controlled studies that correcting abnormalities detected by EGG improves upper gastrointestinal symptoms. Proposed clinical indications for performance of EGG in patients with unexplained nausea, vomiting and dyspeptic symptoms must be validated by prospective controlled investigations.

In an editorial on EGG, Verhagen (2005) stated that because of its low sensitivity and specificity, EGG cannot be used as a diagnostic clinical tool. In certain diseases, EGG may be useful in defining a subgroup of patients. However, at present there is no evidence to support a role for EGG in the diagnostic work-up of patients or in directing therapy.

Abid and Lindberg (2007) examined if there is a correlation between electrical activity measured by EGG and contractile activity of the stomach as measured by antro-duodenal manometry (ADM). These researchers also studied if the underlying motility disorder could be predicted from EGG parameters. They compared 21 parameters measured from EGG with 8 parameters measured from ADM. The ability of EGG to identify the underlying diagnosis was tested by comparing EGG parameters for each diagnosis group against other patients. The study comprised recordings from 148 patients (125 females). Their median age was 45 years (range of 17 to 76). These investigators found few and weak correlations between EGG and ADM. Specifically the correlation between parameters reflecting the response to meal was poor ($r = -0.07$, $p = 0.39$). The discriminatory power of EGG for underlying motility disorder was also low. Patients with slow transit constipation (STC) showed a lower post-prandial power in normogastric (3.7 +/- 0.5 versus 4.0 +/- 0.5) and tachygastric (3.5 +/- 0.4 versus 3.7 +/- 0.4) regions, a lower percentage of time with normogastria [87.2% (56.5 to 100) versus 95.7% (0 to 100)], and a higher percentage of time with tachygastria [9.3% (0 to 33) versus 3.5% (0 to 100)] and bradygastria [1.8% (0 to 20) versus 0% (0 to 17.1)]. Patients with irritable bowel syndrome had a higher percentage of time with normogastria [96.5% (62.5 to 100) versus 93.3% (0 to 100)] and a less unstable dominant frequency as measured by the instability coefficient [15 (3 to 77) versus 24 (2 to 72)]. The authors concluded that EGG and ADM seem to measure different aspects of gastric motor activity but cannot show a spatial correlation. The diagnostic value of EGG is poor, but EGG may have some value for the identification of patients with STC.

It should also be noted that the AGA's medical position statement on diagnosis and treatment of gastroparesis (Parkman et al, 2004) does not mention the use of electrogastrography.

An UpToDate review on “Motility testing: When does it help?” (Lembo, 2014) states that “Routine motility tests such as esophageal manometry, gastric emptying, and anorectal manometry have become readily available. However, the utility of these tests in clinical practice and their appropriate indications are incompletely understood. This topic will review the indications for and utility of esophageal manometry, gastric emptying studies, and anorectal manometry.
Specialized motility tests such as antroduodenal manometry, electrogastrography, and colonic manometry are under development and will not be discussed”.

Also, an UpToDate review on “Approach to the adult with nausea and vomiting” (Longstreth, 2014) states that “Gastroparesis — Nausea may be a feature of gastroparesis but there is a poor correlation among symptoms, gastric dysrhythmias, and gastric emptying rate. Gastric motor dysfunction can be identified by special tests (such as gastric scintigraphy) in a large proportion of these patients. A noninvasive method of recording gastric myoelectrical activity or slow waves from cutaneous leads placed over the stomach (electrogastrography) reveals abnormalities in some patients. There is no evidence that correction of these abnormalities improves symptoms; thus, the role of this procedure in management is uncertain”.

Furthermore, an UpToDate review on “Gastroparesis: Etiology, clinical manifestations, and diagnosis” (Camilleri, 2014) does not mention the use of electrogastrography as a management tool.

A new approach for evaluating gastric motility function in patients with functional dyspepsia and other upper functional gastrointestinal disorders is the use of an ambulatory diagnostic test pill, the SmartPill (SmartPill Corporation; Buffalo, NY). On July 20, 2006, the Unites States Food and Drug Administration cleared the SmartPill GI Monitoring System through the 510(k) process for use as an aid in evaluating patients with suspected motility disorders such as gastroparesis. This wireless, ingestible, medical device assesses pH and pressure in the gastrointestinal lumen. When the capsule reaches the duodenum, the change in pH (from acidic to alkaline) indicates this transition, allowing an assessment of gastric emptying. The single-use, disposable, wireless capsule is slightly larger than a multi-vitamin (26 mm by 13 mm). As it passes through the gastrointestinal tract, miniaturized sensor technology measures pressure, temperature, and pH, as well as real and elapsed time. Acquired data are continuously transmitted over very low power radiofrequencies to a small receiver that can be worn on the patient's belt. Although the capsule normally has a transit time ranging from 24 to 48 hours, it is capable of transmitting data continuously for more than 72 hours in patients with reduced motility. Once the device has passed, the data set is downloaded from the receiver to a laptop computer, and special software provides tools for data analysis and a graphical user interface that indicates when gastric emptying, small bowel/large bowel transit, and total gastrointestinal tract transit time of the capsule has occurred. It should be noted that the SmartPill is intended to supplement, not replace, current gastro-intestinal motility procedures such as endoscopy, duodenal manometry, and gastric emptying scintigraphy.

The BlueCross BlueShield Association Technology Evaluation Center (BCBSA, 2012) concluded that the wireless motility capsule does not meet the TEC criteria. The TEC assessment concluded that the limited body of evidence on the diagnostic characteristics of SmartPill does reveal correlations between SmartPill and other tests that indicate some capability to distinguish diseased from nondiseased persons. The assessment stated, however, because of the types of subjects included in the studies, particularly healthy patients, and the lack of a reference standard for the disease of interest (slow-transit constipation) in some studies, the diagnostic characteristics of SmartPill are uncertain. The assessment
noted that there are no studies that ascertain whether use of the SmartPill in addition to or instead of alternative methods of diagnosis improves patient outcomes.

The Federal Agency for Healthcare Research and Quality (AHRQ, 2011) has commissioned a comparative effectiveness review of the wireless motility capsule compared to other diagnostic technologies for evaluating gastroparesis and constipation. The AHRQ has stated that the current gold standard diagnostic methods for motility disorders include scintigraphy and the use of radiopaque markers. In discussing the considerations for conducting the review, the AHRQ explained: "The SmartPill procedure has been described as having advantages to current standard testing methods including less radiation exposure, a more standardized diagnostic approach, convenience, and a more detailed diagnostic profile; however, the technology may have limited patient selection, contraindications, and may not always avoid radiation exposure" Regarding the current available evidence, the AHRQ stated that "[t]he SmartPill has not been studied extensively in the context of other testing methods, and most available studies have been sponsored by the manufacturer."

The AHRQ (2012) review will address several controversies surrounding the use of the SmartPill wireless motility capsule for gastroparesis. One controversy identified by AHRQ is whether grading the severity of gastric emptying delay affects decisions about patients. They plan to address this question by evaluating data on how treatment decisions differ between scintigraphy and the wireless motility capsule. Another controversy that they plan to address is the lack of information regarding whether or not scintigraphy or wireless motility capsule testing could offer any guidance in assessing response to treatment or whether they would remain purely diagnostic tools. The AHRQ review plans to address this issue by looking for data on treatment response in terms of patient-reported outcomes. The AHRQ stated that it is unclear which populations would benefit most from the wireless motility capsule or which order of testing is best to diagnose patients. The AHRQ noted that the wireless motility capsule testing is currently being used in a complementary fashion as an addition to reference standard tests like scintigraphy. The AHRQ stated that it is controversial whether the wireless motility capsule can replace or should supersede other testing methods.

The AHRQ review (2012) will also examine the evidence for the wireless motility capsule in constipation. Among the advantages of capsule testing identified by AHRQ is that it provides a more complete picture of colonic transit (like whole bowel scintigraphy might if it were more widely available); whereas, radiopaque marker testing, the current reference standard, only offers static imaging. The AHRQ stated however, that it is uncertain at this point whether all the extra data will be useful to change outcomes in any way. The AHRQ stated that more studies must be done as the wireless motility capsule gets adopted into wider use. The AHRQ review will address the controversy regarding the role of wireless motility capsule testing in the diagnostic evaluation of constipation; the AHRQ commented that some experts think that the wireless motility capsule would likely be a complementary test rather than an independent test for patients with this disease.
Kuo and associates (2006) reported their experience with the use of the SmartPill in 86 healthy subjects and 60 patients with documented gastroparesis by scintigraphy. The wireless capsule had a moderate sensitivity and specificity for half-time gastric emptying measurement (71% and 74%, respectively). These findings, originally reported in an abstract, were subsequently published in a full-length article. Kuo et al (2008) compared gastric emptying time (GET) and gastric emptying scintigraphy (GES) by assessing their correlation, and compared GET and GES for discriminating healthy subjects (n = 87) from gastroparetics (n = 61). Fasted subjects were ingested capsule and [(99m)Tc]-SC radiolabeled meal. Images were obtained every 30 minutes for 6 hours. Gastric emptying time and percentage of meal remaining at 2/4 hours were determined for each subject. The sensitivity/specificity and receiver operating characteristic analysis of each measure were determined for each subject. Correlation between GET and GES-4 hour was 0.73 and GES-2 hour was 0.63. The diagnostic accuracy from the receiver operating characteristic curve between gastroparetics and healthy subjects was GET = 0.83, GES-4 hour = 0.82 and GES-2 hour = 0.79. The area-under-the-curve analysis of overall accuracy indicated that there were no statistically significant differences between the SmartPill and scintigraphy for detection of gastroparesis. The 300-min cut-off time for GET gives sensitivity of 0.65 and specificity of 0.87 for diagnosis of gastroparesis. The corresponding sensitivity/specificity for 2- and 4-hour standard GES measures were 0.34/0.93 and 0.44/0.93, respectively. Although the SmartPill was able to distinguish normal state from disease, a case-control study is insufficient for evaluating test characteristics. Prospective, randomized, controlled trials are needed to ascertain the clinical value of the SmartPill. Furthermore, since the SmartPill itself does not empty like a meal from the stomach, the technology is likely to only provide an estimate of upper gastro-intestinal transit.

Cassilly et al (2008) examined if the SmartPill wireless pH and pressure capsule given with a meal empties from the stomach with return of the fasting phase III migrating motor complex (MMC) or during the fed pattern with the solid meal. A total of 15 normal subjects underwent antro-duodenal manometry and ingestion of a radio-labeled meal and the SmartPill. In 5 subjects, emptying of the SmartPill was studied in the fasting period by ingesting the SmartPill with radio-labeled water. The SmartPill emptied from the stomach within 6 hours in 14 of 15 subjects. SmartPill pressure recordings showed high amplitude phasic contractions prior to emptying. SmartPill gastric residence time (261 +/- 22 mins) correlated strongly with time to the first phase III MMC (239 +/- 23 mins; r = 0.813; p < 0.01) and correlated moderately with solid-phase gastric emptying (r = 0.606 with T-50 % and r = 0.565 with T-90 %). Nine of 14 subjects emptied the capsule with a phase III MMC. In 5 subjects, the SmartPill emptied with isolated distal antral contractions. In 5 subjects ingesting only water, SmartPill gastric residence time (92 +/- 44 mins) correlated with the time to the first phase III MMC (87 +/- 30 mins; r = 0.979; p < 0.01). The SmartPill given with a meal primarily empties from the stomach with the return of phase III MMCS occurring after emptying the solid-phase meal. However, in some subjects, the SmartPill emptied with isolated antral contractions, an unappreciated mechanism for emptying of a non-digestible solid.

A study that compared the SmartPill with radiopaque markers for detection of delayed colonic transit in chronically constipated versus normal adults found that
sensitivity of detection was higher for the SmartPill but did not report whether this increase was statistically significant. Rao et al (2009) assessed regional and colonic transit time with the SmartPill in constipated and healthy subjects and compared this with a radiopaque market. Seventy-eight constipated (Rome II) and 87 healthy subjects ingested a 260-kcal meal, a radiopaque marker capsule, and the SmartPill. Subjects wore a data receiver and kept daily stool diaries for 5 days. SmartPill recordings assessed colonic transit time, whole-gut transit time, small-bowel transit time, and gastric emptying time. Abdominal radiographs on days 2 and 5 assessed radiopaque marker transit. Sensitivity, specificity and receiver operating characteristics (ROCs) of each technique and utility were compared. Gastric emptying time, colonic transit time, and whole-gut transit time were slower (p < 0.01) in constipated subjects than controls. Colonic transit time was slower in women than men (p = 0.02). Day 2 and day 5 radiopaque marker transits were slower (p < 0.001) in constipated subjects. Correlation of the SmartPill colonic transit time with radiopaque markers expelled on day 2/day 5 was r = 0.74/r = 0.69 in constipation, and r = 0.70/r = 0.40 in controls, respectively. The diagnostic accuracy of the SmartPill colonic transit time to predict constipation from ROC was 0.73, with a specificity of 0.95. The authors reported that these were comparable with those of day 5 ROM (ROC, 0.71; specificity, 0.95).

Maqbool et al (2009) compared the SmartPill with whole gut transit scintigraphy to determine whether the SmartPill system could serve as a test for measurement of whole gut motility and transit. A total of 10 healthy, asymptomatic subjects underwent simultaneous whole gut scintigraphy and SmartPill assessment of whole gut transit. All subjects completed the study per protocol and experienced natural passage of the pill. Capsule residence time in the stomach correlated with percent gastric retention of the Tc-99 radiolabel at 120 mins (r = 0.95) and at 240 mins (r = 0.73). Small bowel contraction-min(-1) measured by the SmartPill correlated with small bowel transit % (r = 0.69; p = 0.05) and with isotopic colonic geometric center at 24 hrs following ingestion (r = 0.70, p = 0.024). Capsule transit time correlated with scintigraphic assessment of whole gut transit. The authors concluded that SmartPill capsule assessment of gastric emptying and whole gut transit compares favorably with that of scintigraphy. Wireless capsule motility shows promise as a useful diagnostic test to evaluate patients for gastrointestinal transit disorders and to study the effect of prokinetic agents on gastrointestinal transit.

A study comparing the SmartPill to radio-opaque markers in persons with constipation found the SmartPill to be somewhat less accurate, if radioopaque markers are considered the gold standard for assessing colonic transit. Camilleri et al (2010) proposed to validate the SmartPill wireless motility capsule, that measures pH, pressure and temperature, to radio-opaque marker measurement of colon transit in patients with symptomatic constipation evaluated at multiple centers. Of 208 patients recruited, 158 eligible patients underwent simultaneous measurement of colonic transit time (CTT) using radio-opaque markers (Metcalf method, cut-off for delay greater than 67 hours), and wireless motility capsules (WMC) (cut-off for delay greater than 59 hours). The study was designed to demonstrate substantial equivalence, defined as diagnostic agreement greater than 65 % for patients who had normal or delayed radioopaque marker transit. Fifty-nine of 157 patients had delayed radio-opaque marker colonic transit. Transit
results by the 2 methods differed: radio-opaque marker median 55.0 hours [IQR 31.0 to 85.0] and Smartpill (43.5 hours [21.7 to 70.3], p < 0.001). The positive percent agreement between Smartpill and radio-opaque markers for delayed transit was approximately 80%; positive agreement in 47 by SmartPill/59 by radio-opaque marker or 0.796 (95% confidence interval [CI]: 0.67 to 0.98); agreement versus null hypothesis (65%) p = 0.01. The negative percent agreement (normal transit) was approximately 91%: 89 by Smartpill/98 by radioopaque marker or 0.908 (95% CI: 0.83 to 0.96); agreement versus null hypothesis (65%), p = 0.00001. Overall device agreement was 87%. The authors stated that there were significant correlations (p < 0.001) between radio-opaque markers and Smartpill transit (CTT [τ = 0.707] and between radio-opaque markers and combined small and large bowel transit [τ = 0.704]). There were no significant adverse events.

The authors stated that there are potential pitfalls with using all capsules to measure gut transit including technical failures, inability to swallow the capsule, the potential for non-passage of or intestinal obstruction by the capsule in stenosing gut disorders, and greater cost relative to the radio-opaque marker transit method. Application of the Smartpill is contraindicated in patients with known esophageal or intestinal strictures, and children under 18 years of age, in whom validation studies have not yet been completed.

Tack and Janssen (2010) reviewed recent progress in gastro-duodenal motility and sensitivity in health and in disease. The authors stated that although gastric and small intestinal motility remain an important focus of research, including the application of the SmartPill wireless motility monitoring capsule, duodenal sensitivity and low-grade duodenal inflammation are new areas of interest in the pathogenesis of functional dyspepsia. A number of genetic polymorphisms associated with functional dyspepsia are being investigated, but large-scale studies are still lacking.

Timm and colleagues (2011) noted that the SmartPill has not been validated with dietary interventions. Thus, these researchers conducted a controlled cross-over trial to examine if the device could detect a significant difference in transit time after 10 healthy subjects (5 men and 5 women) consumed 9 g of wheat bran (WB) or an equal volume, low-fiber control for 3 days. A paired-t test was used to determine differences in transit times. Colonic transit time decreased by 10.8 (S.D. 6.6) hours (p = 0.006) on the WB treatment. Whole-gut transit time also decreased by 8.9 (S.D. 5.4) hours (p = 0.02) after the consumption of WB. Gastric emptying time (GET) and small-bowel transit time did not differ between treatments. Despite encouraging results, the present study had several limitations including short duration, lack of randomization and unusable data due to delayed gastric emptying of the capsule. With minimal participant burden, the SmartPill technology appears to be a potentially useful tool for assessing transit time after a dietary intervention. This technology could be considered for digestive studies with novel fibers and other ingredients that are promoted for gut health.

Kuo et al (2011) (i) defined prevalence of generalized dysmotility using WMC, (ii) related to symptoms in suspected regional delay, (iii) compared results of WMC testing to conventional transit studies to quantify new diagnoses, and (iv) assessed the impact of results of WMC testing on clinical decisions. Wireless motility capsules transits were analyzed in 83 patients with suspected gastroparesis, intestinal dysmotility, or slow transit constipation. Isolated regional
delays were observed in 32% (9% stomach, 5% small bowel, 18% colon). Transits were normal in 32% and showed generalized delays in 35%. Symptom profiles were similar with normal transit, isolated delayed gastric, small intestinal, and colonic transit, and generalized delay (p = NS). Compared to conventional tests, WMC showed discordance in 38% and provided new diagnoses in 53%. Wireless motility capsules testing influenced management in 67% (new medications 60%; modified nutritional regimens 14%; surgical referrals 6%) and eliminated needs for testing not already done including gastric scintigraphy (17%), small bowel barium transit (54%), and radio-opaque colon marker tests (68%).

The authors concluded that WMC testing defines localized and generalized transit delays with suspected gastroparesis, intestinal dysmotility, or slow transit constipation. Symptoms do not predict the results of WMC testing. Wireless motility capsules findings provide new diagnoses in greater than 50%, may be discordant with conventional tests, and can influence management by changing treatments and eliminating needs for other tests. They stated that these findings suggested potential benefits of this method in suspected dysmotility syndromes and mandate prospective investigation to further define its clinical role.

Brun et al (2012) evaluated the ability of WMC to detect phase III MMC and correlated it with the simultaneous measurements by ADM. A total of 18 patients underwent simultaneous ADM and WMC. Migrating motor complexes were identified first on ADM and then correlated with WMC events occurring simultaneously. Frequency of contractions per min, area under the pressure curve (AUC), and motility index (MI) and criteria for amplitude thresholds of contractions representing MCCs on WMC tracings were defined. In 18 patients, a total of 29 MMCs were recorded by ADM. Wireless motility capsule detected 86% of MMC events measured by ADM. Hundred percent (10/10) of MMCs in stomach were detected by WMC, whereas 79% (15/19) of MMCs were detected in small bowel (SB). The sensitivity and specificity of WMC high amplitude contractions to represent phase III MMC were 90% and 71.8% in the stomach; 73.7% and 84.7% in SB, respectively, and negative predictive value was 99.9% in both regions. The authors concluded that WMC was able to detect the phase III MMCs as the high amplitude contractions with good fidelity. Wireless motility capsule does not detect the propagation of MMC. Using the pressure thresholds, WMC can detect high amplitude contraction representing phase III MMC with favorable sensitivity/specificity profile and 99.9% negative predictive value. They stated that this observation may have clinical significance, as the absence of high amplitude contractions recorded by WMC during fasting state suggested absence of MMCs; further studies are needed to determine the potential use of these results in clinical practice for diagnosis and profiling of gastro-intestinal motility disorders.

Tran et al (2012) noted that the WMC is an ambulatory non-invasive and non-radioactive diagnostic sensor that continuously samples intra-luminal pH, temperature, and pressure as it moves through the gastro-intestinal (GI) tract. These researchers summarized the data obtained in clinical trials with the WMC and discussed its role in clinical practice. The United States Food and Drug Administration has approved the SmartPill GI monitoring system for the evaluation of gastric emptying time in patients with suspected gastroparesis, the evaluation of colonic transit time in patients with suspected chronic constipation, and for the characterization of pressure profiles from the antrum and duodenum. Clinical studies have shown that WMC-measured GI transit times can distinguish patients
with motility abnormalities similarly to conventional testing. However, the WMC offers the advantage of providing a full GI-tract profile, enabling the detection of multi-regional GI transit abnormalities in patients with suspected upper or lower GI dysmotility. The WMC also characterizes pressure profiles of the GI tract and impaired pressure profile limits are reported for the antrum and duodenum. In comparison with manometry, interpretations of pressure measurements obtained by the WMC are limited by an inability to detect a peristaltic pressure wave front, and further investigation is needed to develop clinical applications. The authors concluded that WMC is a novel technology offering a non-invasive, non-radioactive, standardized method to evaluate intra-luminal pH, temperature, and pressure, allowing for the measurement of gastric, small bowel, colon, and whole GI transit times. As a single ambulatory test, it allows for an assessment of isolated and diffuse motility transit abnormalities. Interpretation of frequency of contractions (Ct) measurements obtained by the WMC is limited compared with manometry testing, but continues to evolve. Clinical studies with the WMC indicated that it should be considered for the evaluation of regional and whole gut transit time in patients with suspected upper or lower dysmotility, particularly if there are concerns about multi-regional dysmotility. The drawbacks of this study were "while the WMC provides a full GI tract-transit profile in a standardized protocol, the pressure profiles are limited by nonstationary, single point pressure measurements throughout the GI tract. As a new method of measuring GI Ct, new standards need to be developed and validated before the relevance of this information is clear .... The WMC, with only one pressure sensor, is unable to detect a pressure wave front, which limits its utility in comparison to traditional manometric testing. However, with the invasive nature and limited availability of manometry, the WMC may have significant potential as further investigation continues to evolve the clinical utility of WMC pressure data. The WMC cannot distinguish the absolute time of emptying of a meal or distinguish between liquid and solid emptying; rather it measures the total meal emptying. Furthermore, the WMC measures gastric emptying indirectly through the use of a physiologic meal. Scintigraphy testing leads to a more physiologic assessment of transit time. As a nondigestible capsule that needs to be ingested, the WMC should not be administered to those patients with suspected strictures, fistulas, or GI obstructive symptoms. In addition, it should be used with caution for anyone with a history of gastric bezoars, dysphagia, or disorders of swallowing, recent GI surgery, Crohn’s disease, or diverticulitis".

Rauch et al (2012) used a novel WMC to compare gastric emptying and SB transit times in critically ill trauma patients and healthy volunteers. These investigators evaluated gastric emptying, SB transit time, and total intestinal transit time in 8 critically ill trauma patients. These data were compared with those obtained in 87 healthy volunteers from a separate trial. Data were obtained with a motility capsule that wirelessly transmitted pH, pressure, and temperature to a recorder attached to each subject's abdomen. The gastric emptying time was significantly longer in critically ill patients (median of 13.9; interquartile range [IQR]: 6.6 to 48.3 hours) than in healthy volunteers (median of 3.0; IQR: 2.5 to 3.9 hours), p < 0.001. The SB transit time in critically ill patients was significantly longer than in healthy volunteers (median of 6.7 hours; IQR: 4.4 to 8.5 hours versus median of 3.8 hours; IQR: 3.1 to 4.7 hours), p = 0.01. Furthermore, the capsules passed after 10 (IQR: 8.5 to 13) days in the critical care group and 1.2 (IQR: 0.9 to 1.9)

days in healthy volunteers (p < 0.001). The authors concluded that both gastric emptying and SB transit were delayed in critically ill trauma patients. The drawbacks of this study were the small number of critically ill patients, and exclusion of patients with increased intra-abdominal pressure, open abdominal injury, and exploratory laparotomies. Also, these researchers measured gastric emptying and SB transit time only once during the ICU stay because it is not possible to start a new capsule examination until the previous one has passed from the body. Although delayed gastric emptying is most common in the first 3 days after ICU admission, the authors cannot exclude disturbance of intestinal motility later in the critical care course. Furthermore, both enteral feeding as well as anti-acid therapies can alter intra-luminal pH, complicating identification of the capsule’s transition from the stomach to small intestine. The authors stated that "[d]espite the use of H2 blockers, all patients had a distinct pH pattern to identify the passage of the capsule. Nguyen et al has shown in a retrospective study that morphine/midazolam and propofol can alter gastric emptying. It seems that patients under propofol-based sedation have a lower incidence of delayed gastric emptying. Although sedation and analgesia requirements were similar among the critically ill group, we cannot exclude that the pharmacologic effect of propofol/midazolam and fentanyl/morphine could have contributed to the prolonged gastric emptying time and small bowel transit time".

Willis and associates (2011) explored the feasibility and sensitivity of a new technology for measuring GET in appetite research, and compared appetite after subjects consumed macronutrient- and fiber-matched liquid and solid meals. A total of 14 women (body mass index [BMI] of 21.2 +/- 0.3) participated in this randomized, cross-over study. On 2 separate days, fasted subjects consumed liquid (fruit juices and skim milk) and solid (oatmeal, blueberries, and apples) breakfasts. Both meals had 10 g of fiber and 410 kcal. Gastric emptying time was assessed with the SmartPill GI Motility System, appetite was assessed with visual analog scales, and food intake was measured at lunch. Despite the same amount of fiber, GET was about 1 hour longer after the oatmeal than after the liquids. Subjects were less hungry after the oatmeal than after the liquids. Satisfaction and fullness were marginally improved with the oatmeal compared to the liquids. There was a negative association between GET and hunger. Lunch-time food and beverage intake did not differ between treatments. The authors concluded that the SmartPill appears feasible and sensitive in appetite research, but has limitations.

Weinstein et al (2013) stated that GERD and gastric acid hyper-secretion respond well to suppression of gastric acid secretion. However, clinical management and research in diseases of acid secretion have been hindered by the lack of a non-invasive, accurate and reproducible tool to measure gastric acid output (GAO). Thus, symptoms or, in refractory cases, invasive testing may guide acid suppression therapy. These researchers presented and validated a novel, non-invasive method of GAO analysis in healthy subjects using a wireless pH sensor, SmartPill (SP) (SmartPill Corporation, Buffalo, NY). A total of 20 healthy subjects underwent conventional GAO studies with a nasogastric tube. Variables impacting liquid meal-stimulated GAO analysis were assessed by modelling and in-vitro verification. Buffering capacity of Ensure Plus was empirically determined. SmartPill GAO was calculated using the rate of acidification of the Ensure Plus meal. Gastric emptying scintigraphy and GAO studies with radiolabelled Ensure Plus and SP assessed emptying time, acidification rate and mixing; 12 subjects
had a second SP GAO study to assess reproducibility. Meal-stimulated SP GAO analysis was dependent on acid secretion rate and meal-buffering capacity, but not on gastric emptying time. On repeated studies, SP GAO strongly correlated with conventional basal acid output (BAO) ($r = 0.51, p = 0.02$), maximal acid output (MAO) ($r = 0.72, p = 0.0004$) and peak acid output (PAO) ($r = 0.60, p = 0.006$). The SP sampled the stomach well during meal acidification. The authors concluded that SP GAO analysis is a non-invasive, accurate and reproducible method for the quantitative measurement of GAO in healthy subjects. They stated that SP GAO analysis could facilitate research and clinical management of GERD and other disorders of gastric acid secretion. These findings from a feasibility study using health subjects need to be validated by well-designed studies using patients with gastric disorders.

The American College of Gastroenterology's clinical guideline on "Management of gastroparesis" (Camilleri et al, 2013) noted that “Alternative approaches for assessment of gastric emptying include wireless capsule motility testing and 13C breath testing using octanoate or spirulina incorporated into a solid meal; they require further validation before they can be considered as alternates to scintigraphy for the diagnosis of gastroparesis”. (Conditional recommendation, moderate level of evidence).

In a review on radionuclide gastro-esophageal motor studies, Mariani et al (2004) noted that radionuclide transit/emptying scintigraphy provides a means of characterizing exquisite functional abnormalities with a set of low-cost procedures that are easy to perform and widely available, entail a low radiation burden, closely reflect the physiology of the tract under evaluation, are well-tolerated and require minimum cooperation by patients, and provide quantitative data for better inter-subject comparison and for monitoring response to therapy. Despite the relatively low-degree of standardization both in the scintigraphic technique per se and in image processing, these methods have shown excellent diagnostic performance in several function or motility disorders of the upper digestive tract. Dynamic scintigraphy with a radioactive liquid or semi-solid bolus provides important information on both the oropharyngeal and the esophageal phases of swallowing, thus representing a useful complement or even a valid alternative to conventional invasive tests (e.g., stationary esophageal manometry) for evaluating abnormalities of oropharyngo-esophageal transit. Clinical applications of esophageal transit scintigraphy include disorders such as nutcracker esophagus, esophageal spasm, non-cardiac chest pain of presumed esophageal origin, achalasia, esophageal involvement of scleroderma, and gastro-esophageal reflux and monitoring of response to therapy. Scintigraphy with a radiolabeled test meal represents the gold standard for evaluating gastric emptying, whereas more recent radionuclide methods include dynamic antral scintigraphy and gastric SPECT for assessing gastric accommodation. Clinical applications of gastric-emptying scintigraphy include, among others, evaluation of patients with dyspepsia and evaluation of gastric function in various systemic diseases affecting gastric emptying.

Maurer and Parkman (2006) stated that nuclear medicine offers a variety of studies for evaluating motility throughout the gastro-intestinal tract. Gastric emptying remains the "gold standard" for studying gastric motor function, but its application in most centers remains limited to measuring only total gastric
emptying in spite of data that show assessment of both fundal and antal function is of clinical value for evaluating patients with dyspepsia. Smith and Ferris (2003) noted that the diagnosis of diabetic gastroparesis may be confirmed by demonstrating gastric emptying delay during a 4-hr scintigraphic study. This is in agreement with the report by Stassen (2005) who noted that the diagnosis of diabetic gastroparesis may be confirmed by scintigraphy assessment of gastric emptying, preferably using a solid meal. Feigenbaum (2006) stated that the gold standard for the diagnosis of gastroparesis is a gastric emptying study. Furthermore, the AGA's medical position statement on diagnosis and treatment of gastroparesis (Parkman et al, 2004) stated that gastric emptying scintigraphy of a radiolabeled solid meal is the best accepted method to test for delayed gastric emptying.

Ziessman and associates (2009) examined if a study of clear liquid gastric emptying has added value for the diagnosis of gastroparesis over a study of solid emptying alone. A total of 101 patients underwent both solid and liquid gastric-emptying studies, acquired sequentially on the same day. A 30-min (1-min frames) liquid study (300 ml of water with 7.4 MBq [0.2 mCi] of (111)In-diethylenetriaminepentaacetic acid) was followed by a standardized 4-hr solid-meal study (a (99m)Tc-sulfur colloid-labeled egg-substitute sandwich meal). Emptying was quantified as a best-fit exponential emptying rate (T1/2) for liquids and percentage emptying at 4 hrs for solid emptying. A total of 30 healthy volunteers underwent a study of clear liquid emptying to establish normal values. The results of the liquid and solid studies were compared. (111)In liquid downscatter into the subsequent (99m)Tc solid meal results was analyzed. The upper range of normal for clear liquid emptying (T1/2) for healthy volunteers was 22 mins (mean +/- 3 SDs) and 19 mins (mean +/- 2 SDs). Of 101 patients, delayed emptying was found in 36 % of liquid and 16 % of solid studies. Of all patients with normal solid emptying, 32 % had delayed liquid emptying. (111)In downscatter into the (99m)Tc window was not generally significant. The authors concluded that for the detection of gastroparesis, a 30-min study of clear liquid gastric-emptying has considerable added diagnostic value over a study of solid emptying alone.

Hyett et al (2009) evaluate the prognostic value of gastric emptying studies on the morbidity associated with diabetic gastroparesis. This was a parallel cohort study of 3 groups. Group A (n = 94) contained diabetics (type 1 and type 2) with classic symptoms of gastroparesis (including early satiety, post-prandial fullness, bloating, abdominal swelling, nausea, vomiting, and retching) and delay in radionucleotide gastric emptying study. Group B (n = 94) contained diabetic subjects with classic symptoms of gastroparesis but negative scintigraphy. Group C (n = 94) contained diabetic subjects without symptoms of gastroparesis. Data were gathered on the number of days hospitalized and hospitalizations, office visits, emergency department (ED) visits, death rate, glycosylated hemoglobin levels (HbA1c), medications and past medical history. Group A had significantly more hospital days per 1,000 patient days (25.5) than both Group B (5.1; p < 0.01) and Group C (2.3; p < 0.01). Group A also had significantly more hospitalizations, office visits and ED visits than both Group B and Group C. Deaths and mean HbA1c level did not differ between the groups. Group A patients were more likely to have cardiovascular disease (19.2 % versus 6.4 % A versus C; p < 0.05), hypertension (63 % versus 43 % A versus C; p = 0.005) and retinopathy (33 % versus 11.7 % A
versus C; p < 0.001). The authors concluded that a delayed radionuclide gastric emptying study predicts negative health outcomes in diabetics with symptoms of gastroparesis. They identified a correlation between diabetic gastroparesis and cardiovascular disease, hypertension and retinopathy which may indicate an underlying vascular etiology.

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 evaluated clinical outcomes in children with chronic constipation evaluated by OTT and CM studies. A total of 24 children with chronic constipation (12 girls; median age of 12 years [3 to 18 years]; median symptoms of 87 months [6 to 186 months]) who underwent OTT and CM studies were reviewed. The OTT was determined using commercially available Sitzmarks. Patients were studied for a median of 23 months (4 to 60 months) and outcomes reviewed. All 5 children with normal OTT had normal CM; however, only 47 % (9/19) of children with slow OTT had an abnormal CM. The abnormal CM findings were total colonic pseudo-obstruction in 3 and left colonic pseudo-obstruction in 6 children. Of the 9 children with abnormal CM, 5 were managed surgically, 1 with medicine escalation, and 3 were lost to follow-up; all 6 children with known follow-up have more bowel movements and less soiling. Of the 15 children with normal CM, 10 were managed with medication escalation, 3 with behavioral intervention, and 2 surgically. Of these 15 children, 8 improved, 1 did not change, 2 worsened, and 4 were lost to follow-up. The authors concluded that 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. Therefore, 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.

An UpToDate review on “Etiology and diagnosis of delayed gastric emptying” (Camilleri, 2013) states that “A potential alternative to manometry is a capsule ("SmartPill"), which is swallowed, and can simultaneously measure phasic pressure amplitudes and pH as it traverses different segments of the gastrointestinal tract. The characteristic change in pH between stomach and small intestine provides an indication of the gastric emptying time for a non-digestible solid > 1 cm long. The SmartPill given with a meal empties primarily during the phase III MMCs occurring after emptying the solid-phase meal. However, in some patients, the SmartPill empties with isolated antral contractions, an unappreciated mechanism for emptying of a non-digestible solid”.

Conklin (2013) stated that for several decades esophageal manometry has been the test of choice to evaluate disorders of esophageal motor function. The recent introduction of high-resolution manometry for the study of esophageal motor function simplified performance of esophageal manometry, and revealed previously unidentified patterns of normal and abnormal esophageal motor function. Presentation of pressure data as color contour plots or esophageal pressure topography led to the development of new tools for analyzing and classifying esophageal motor patterns. The current standard and still developing approach to do this is the Chicago classification. The author concluded that while
this methodical approach is improving the diagnosis of esophageal motor disorders, it currently does not address all motor abnormalities.

Vela (2014) stated that treatment options for achalasia include oral pharmacologic therapy, endoscopic injection of botulinum toxin, pneumatic dilation, and myotomy (conventionally by laparoscopy, but more recently by an endoscopic approach). Oral pharmacologic agents have fallen out of use because of insufficient efficacy and frequent side effects. Endoscopic injection of botulinum toxin is safe and has good short-term effectiveness, but as the effect invariably wears off after a few months, this treatment is reserved for patients who are not candidates for more definitive treatments. Pneumatic dilation and surgical myotomy are currently considered the most effective treatments, with similar effectiveness in randomized controlled trials (RCTs) with follow-up of up to 2 years. The risk/benefit ratio and choice of therapy depend on patient characteristics (e.g., age, co-morbidities, disease stage, prior treatments), patient's preference, and locally available expertise. Treatment of patients who fail or relapse after initial therapy is challenging and the success rate of pneumatic dilation or myotomy in this group is lower compared with previously untreated patients. The recently developed peroral endoscopic approach to myotomy has achieved excellent results in early uncontrolled studies, but high-quality RCTs are needed to ensure widespread adoption is reasonable. The authors also noted that retrospective data suggested that achalasia subtypes as defined by HREPT may guide treatment choice, but confirmation in prospective outcome studies is awaited.

Rozov-Ung et al (2014) evaluated the ability of a wireless motility capsule to detect drug effects on GET and gastric contractility. A total of 15 healthy adults were administered in random order saline, erythromycin IV 150 mg, or morphine IV 0.05 mg/kg body weight. Subjects ate a standard meal after each infusion, and subsequently ingested the motility capsule. Data were recorded for 8 hours, and the results were analyzed using the manufacturer's software. Gastric emptying time was significantly faster after erythromycin than either saline or morphine. Morphine tended to delay emptying of the capsule compared to saline. There was a trend toward a greater frequency of gastric contractions with erythromycin and a reduced frequency of gastric contractions with morphine that did not reach statistical significance. The authors concluded that a wireless motility capsule successfully detected acceleration of gastric emptying induced by erythromycin, and retardation of gastric motility caused by morphine. They stated that these results indicated that a wireless motility capsule is a promising technique to assess pharmacologic effects on gastric transit and contractility and aid in development of drugs for gastric motor disorders.

An UpToDate review on “Motility testing: When does it help?” (Lembo, 2015) states that “Specialized motility tests such as antroduodenal manometry, electrogastrography, and colonic manometry are under development and will not be discussed”.

Rao et al (2011) noted that scintigraphy is recommended for detection of altered small intestinal transit in subjects with suspected diffuse GI motility disorder but is available in a limited number of centers.

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) and the European Association of Nuclear Medicine (EANM)'s practice guideline for small-
bowel and colon transit (Maurer et al, 2013) noted that “A position paper from the American Neurogastroenterology and Gastrointestinal Motility Society and the European Society of Neurogastroenterology and Motility states that scintigraphy is recommended for “detection of altered small-intestine transit in subjects with suspected diffuse gastrointestinal motility disorder” and that colon transit scintigraphy “offers reproducible and accurate performance,” as it measures whole-gut and regional colon transit in patients with suspected colonic motility disorders or more diffuse disorders involving the stomach or small intestine”.

### CPT Codes / HCPCS Codes / ICD-9 Codes

#### Electrogastrography or colonic motility studies (colonic manometry):

**CPT codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>91117</td>
<td>Colon motility (manometric) study, minimum 6 hours continuous recording (including provocation tests, eg, meal, intracolonic balloon distention, pharmacologic agents, if performed), with interpretation and report</td>
</tr>
<tr>
<td>91132</td>
<td>Electrogastrography, diagnostic, transcutaneous</td>
</tr>
<tr>
<td>91133</td>
<td>Electrogastrography, diagnostic, transcutaneous; with provocative testing</td>
</tr>
</tbody>
</table>

#### High resolution esophageal pressure topography (HREPT):

**CPT codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0240T</td>
<td>Esophageal motility (manometric study of the esophagus and/or gastroesophageal junction) study with interpretation and report; with high resolution esophageal pressure topography</td>
</tr>
<tr>
<td>0241T</td>
<td>with stimulation or perfusion during high resolution esophageal pressure topography study (eg, stimulant, acid or alkali perfusion) (List separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

#### Wireless capsule for measuring gastric emptying parameters (SmartPill GI Monitoring System):

**CPT codes not covered for indications listed in the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>91112</td>
<td>Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report</td>
</tr>
</tbody>
</table>

**ICD-9 codes not covered for indications listed in the CPB [not all-inclusive]:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>530.0</td>
<td>Diseases of esophagus, stomach and duodenum</td>
</tr>
<tr>
<td>539.89</td>
<td></td>
</tr>
</tbody>
</table>
Gastrointestinal Function: Selected Tests

560.0 - 564.9  Diseases of intestines

751.3  Hirschsprung's disease and other congenital functional disorders of the colon

787.01 - 787.99  Symptoms involving digestive system

789.00 - 789.9  Other symptoms involving abdomen and pelvis

Radionuclide gastric emptying study:

CPT codes covered if selection criteria are met:

78264  Gastric emptying study

ICD-9 codes covered if selection criteria are met:

536.3  Gastroparesis

Magnetic resonance enterography:

CPT codes covered if selection criteria are met:

72197  Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s), followed by contrast material(s) and further sequences

74183  Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s) followed by contrast material(s) and further sequences

ICD-9 codes covered if selection criteria are met [not all-inclusive]:

152.0 - 152.9  Malignant neoplasm of small intestine, including duodenum

555.0 - 555.9  Regional enteritis [Crohn's disease]

562.00 - 562.03  Diverticula of small intestine

The above policy is based on the following references:

Electrogastrography:


34. Lembo AJ. Motility testing: When does it help? Last reviewed February 2014. UpToDate Inc., Waltham, MA.
35. Longstreth GF. Approach to the adult with nausea and vomiting. Last reviewed February 2014. UpToDate Inc., Waltham, MA.
36. Camilleri M. Gastroparesis: Etiology, clinical manifestations, and diagnosis. Last reviewed February 2014. UpToDate Inc., Waltham, MA.
37. Lembo AJ. Motility testing: When does it help? UpToDate Inc., Waltham, MA. Last reviewed February 2015.

Colonic Motility Studies:


22. Camilleri M. Etiology and diagnosis of delayed gastric emptying. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed February 2013.

**Wireless Capsule for Measuring Gastric Emptying (SmartPill GI Monitoring System):**


23. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Wireless motility capsule in the diagnosis and evaluation of gastroparesis or slow-transit constipation. TEC Assessment Program. Chicago, IL: BCBSA; October 2012;27(4).


Radionuclide Gastric Emptying Study:


High Resolution Esophageal Pressure Topography (HREPT):
