

Wireless Capsules for the Evaluation of Suspected Gastric and Intestinal Motility Disorders

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Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Investigational or experimental services are not covered. This includes any drug, device, procedure, or service provided under the investigational arm of a clinical trial or clinical study. These services are excluded from coverage under benefits.

Note: Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders is addressed separately in medical policy 00137.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers wireless motility capsules (e.g., MotiliCapTM*, Atmo[®]* Gas Capsule System) for evaluation of all conditions including, but not limited to the following to be **investigational**.*

- Suspected gastric motility disorders (e.g., gastroparesis); **or**
- Suspected intestinal motility disorders (e.g., constipation).

Background/Overview

The SmartPill capsule was designed to measure pH, temperature and pressure throughout the gastrointestinal (GI) tract and transmit measurements via radio signals to an external recording device. In the stomach, the SmartPill has been used to assess gastric emptying in individuals with suspected gastroparesis. In the intestine, the SmartPill has been used to assess small and large bowel transit times in those with chronic constipation or other motility disorders. The MotiliCap similarly measures gastric, small bowel, and colonic transit times using pH, pressure, and temperature data which transmits this information to a wearable receiver as it progresses through the GI tract. The Atmo Gas Capsule System measures gases in the GI tract and transmits the data wirelessly. The device aids in measuring GI tract transit times which are used to evaluate motility disorders like gastroparesis or slow transit constipation.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A WMC device, known as the SmartPill Motility Testing System (Medtronic), has been cleared for marketing by the U.S. Food and Drug Administration (FDA). According to the FDA 510(k)

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documents, the SmartPill is indicated for use in evaluating individuals with suspected delayed gastric emptying (gastroparesis) as well as for the evaluation of colonic transit in those with chronic constipation. The SmartPill measures pH, pressure and temperature throughout the gastrointestinal tract. This data is then transmitted from the capsule via radio signal to an individually worn data receiver and downloaded to a computer in the physician's office for analysis and review. The recorded physiological measurements are used to determine GET, total transit time, and combined small-large bowel transit time. In addition, pressure contraction patterns from the antrum and duodenum are used to calculate motility indices. In June 2023, Medtronic announced they would halt manufacturing of the SmartPill. They will continue to fill orders with available inventory and they do not have plans to create an alternative device.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

This document addresses the use of wireless motility capsules (WMCs), including SmartPill, MotiliCap, and the Atmo Gas Capsule System, for assessment of gastric emptying and regional gastrointestinal (GI) transit times in suspected motility disorders. The document reviews comparative studies with gastric emptying scintigraphy (GES) and radiopaque marker (ROM) testing, noting variable agreement and limited evidence demonstrating impact on clinical outcomes or management decisions.

Discussion

Wireless Motility Capsule (WMC) for the Evaluation of Suspected Gastroparesis

An early prospective, multicenter study comparing the SmartPill WMC to GES was published by Kuo and colleagues in 2008. The study enrolled 87 healthy participants and 61 participants with known gastroparesis. Participants simultaneously ingested the wireless capsule and a radiolabeled meal, permitting a head-to-head comparison. The investigators did not indicate whether outcomes were interpreted in a blinded fashion. At 4 hours, the correlation between the 2 techniques was 0.73, which exceeded the prespecified target correlation. Limitations included technical device failures resulting in missing gastric emptying time (GET) data and protocol issues in which early capsule emptying occurred in some participants when the capsule was ingested before the meal. The study population showed gender imbalance consistent with clinical gastroparesis demographics, and reliance on scintigraphy as the comparator introduces inherent methodological differences, as the capsule measures emptying of an indigestible solid during migrating motor complex activity rather than digestible meal emptying. In a secondary analysis of data from 100 study participants, reported by Sarosiek and colleagues (2010), GET, colon transit time (CTT) and whole gut transit times (WGTT) but not small bowel transit time (SBTT) were noted to be longer in gastroparetics than in healthy controls. This study was limited in that it did not include individuals with suspected gastroparesis, the population of interest.

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A 2013 comparative effectiveness review by the Agency for Healthcare Research and Quality (AHRQ) identified seven studies comparing WMC and GES for diagnosing gastroparesis. Although the AHRQ report found that the diagnostic accuracy of WMC and GES were similar, the strength of evidence was determined to be low which indicated “low confidence that the evidence reflects the true effect.” The main limitations contributing to the low strength of the evidence were that participant eligibility criteria and criteria for positive test findings were not clearly pre-specified. Moreover, most studies had limited durations of follow-up.

Hasler (2014) published an expert review that summarized the rationale, methodology, performance characteristics, safety profile, and clinical utility of the SmartPill WMC for evaluating suspected gastroparesis and other GI motility disorders. The author noted that the WMC measures intraluminal pH, pressure, and temperature to determine GET based on the characteristic pH rise at pyloric passage, and also quantifies small bowel and colonic transit as well as regional contractile activity. Published data show moderate to strong correlation between WMC GETs and 4-hour scintigraphy, with comparable sensitivity and specificity for detecting delayed emptying. Additional potential advantages include detection of extragastric transit delays and characterization of hypomotility patterns. Safety data indicate low rates of technical failure and rare capsule retention, typically manageable without surgery. Limitations include that most studies involve small sample sizes, retrospective designs, or enrollment of individuals with pre-established diagnoses rather than newly evaluated symptomatic cohorts. Evidence supporting incremental clinical benefit over scintigraphy is limited and rated as low strength in systematic assessments. Symptom physiology correlations remain weak, and prospective data demonstrating impact on clinical outcomes or management decisions are lacking. Differences in physiologic mechanisms between digestible meal emptying (scintigraphy) and nondigestible capsule passage may contribute to test discordance. Overall, while WMC offers a radiation-free, office-based alternative with broader transit assessment capability, further large prospective trials are needed to clarify its role in routine clinical practice.

Hasler and colleagues (2018) compared WMC and GES in individuals with suspected gastroparesis, but did not report diagnostic accuracy or the impact on management decisions or health outcomes. In the study, 209 individuals with gastroparesis symptoms for at least 12 weeks with no evidence of organic disease underwent WMC and GES on different days. Individuals ceased taking medications prior to WMC testing. Blinding was not discussed. The overall agreement between GET and delayed 4-hour scintigraphic retention was 52.8% (kappa, 0.12). Agreement between GET and 2-hour scintigraphic retention was 58.7% (kappa, 0.16). The study investigators noted that device agreement was lower than that in the earlier study by Kuo and colleagues (2008), discussed above, and hypothesized that this difference may be due in part to the tests being performed on separate days in the current investigation whereas they were done on the same day in the Kuo study. Other limitations include incomplete data acquisition in a subset of participants due to device retention duration or signal loss and limited ability to determine CTT in all cases. Glycemic control was not continuously monitored in diabetic participants, and some maintenance medications that may influence motility were permitted, which could affect results. The observational design precludes causal inference regarding relationships between motor abnormalities and symptoms, and agreement between WMC and scintigraphy was modest, reflecting methodological differences in measuring indigestible versus digestible solid emptying.

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Several studies have compared simultaneous WMC and GES in individuals with suspected gastroparesis. In 2019, Lee and colleagues reported on delayed GET in 167 individuals with gastroparesis who were assessed simultaneously by WMC and GES. Delayed gastric emptying by WMC was defined as more than 5 hours before passage of the capsule into the duodenum and delayed emptying by GES was defined as at least 10% meal retention at 4 hours. Delayed GET by WMC occurred in 53 individuals (34.6%) and delayed gastric emptying by GES occurred in 39 individuals (24.5%). There was an overall device agreement between WMC and GES of 75.7%. Severely delayed gastric emptying was identified in 21 individuals (13.8%) by WMC and 11 individuals (7%) with GES. Agreement between WMC and GES for severe delayed gastric emptying was 38%. Significantly higher proportions of individuals with delayed and severely delayed emptying were identified by WMC. Limitations include the high proportion of individuals with normal gastric emptying, reflecting real-world referral patterns but potentially affecting diagnostic yield interpretation; a predominantly white female cohort limiting broader demographic generalizability; and protocol elements such as administration of a liquid meal after capsule ingestion, which may have influenced GETs in some cases. The study did not correlate physiological findings with symptom severity or clinical outcomes, limiting conclusions regarding clinical impact. Additionally, funding and investigator relationships with the device manufacturer introduce potential bias.

In 2020, Sangnes and colleagues reported on 72 individuals with diabetes mellitus and suspected gastroparesis. The correlation between WMC and 4-hour GES was $r=0.74$ ($p<0.001$). At a cutoff of 300 minutes for GET with WMC, the sensitivity compared with GES 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 they included the population of interest, the Lee and Sangnes studies did not address the impact of diagnosis by WMC and GES on management of individuals or health outcomes.

Thwaites (2026) reported on a prospective study that evaluated regional colonic metabolic activity in healthy adults using tandem and repeat ingestion of a pH-sensing WMC and a gas-sensing capsule capable of measuring hydrogen and carbon dioxide concentrations. Colonic pH demonstrated a proximal-to-distal increase in most individuals, while carbon dioxide concentrations were consistently higher distally and showed strong proximal distal correlation, suggesting greater overall microbial metabolic activity in the distal colon. Hydrogen concentrations displayed greater inter-individual variability, with proximal distal gradients varying across participants, likely reflecting differences in substrate availability and microbial hydrogen utilization. Tandem and repeat capsule studies demonstrated minimal measurement bias and acceptable intra-individual variance, supporting technical reproducibility. Limitations include the restriction to healthy individuals, limiting generalizability to populations with GI disease. The carbon dioxide sensor cannot distinguish methane from carbon dioxide, potentially confounding interpretation of fermentation patterns, and no concurrent breath methane testing was performed. There is no established gold standard for in vivo colonic gas measurement, and dietary intake was not standardized or systematically recorded, limiting interpretation of inter-individual variability. Additionally, precise anatomic localization within colonic segments beyond proximal and distal quartiles is not possible, and distal measurements demonstrated

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greater variability. Further studies are needed to evaluate clinical applications and disease-specific patterns.

WMC for the Evaluation of Suspected Chronic Constipation

Chronic constipation may be associated with a prolonged CTT or WGTT, both of which are typically measured using ROMs. Validation of the WMC to evaluate CTT or WGTT requires directly comparative studies with conventional ROM and blinded interpretation of results. In addition, the diagnosis of chronic constipation is based predominantly on clinical symptoms; therefore, studies should ideally document how measurements of transit times contribute to management of the condition (i.e., clinical utility).

A study by Camilleri and colleagues (2010) compared the WMC to ROM measurements of colon transit. Of the 208 participants recruited 180 individuals with self-reported symptoms of constipation were enrolled in the multicenter trial. The study participants ingested both the WMC and ROM. After exclusions and missing data, the assessment of CTT was based on comparisons between WMC and ROM in 157 participants, and comparison between small and large bowel transit time (SLBTT) by WMC and ROM in 154 participants, a loss to follow-up of 75.5% and 74%, respectively. Study results indicated that 59 of 157 participants had delayed ROM colon transit. Overall device agreement was reported as 86%. There were correlations reported between ROM and WMC transit and between ROM and combined SLBTT. Estimates of CTT and SLBTT were calculated by a team reported as being blinded to the ROM transit results. Adverse events reported during the trial included the inability of 2 participants to swallow the WMC and 1 case each of abdominal cramping, nausea and loose or soft stools recorded as possibly related to the WMC. The authors noted potential pitfalls of 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 ROM transit method.”

A smaller study by Rao and colleagues (2009) compared transit times in both constipated (n=78) and healthy participants (n=87) measured simultaneously with the WMC and ROM. The WMC estimated the SBTT based on pH changes as the capsule entered the duodenum (increase in pH) and then passed into the cecum (decrease in pH). The CTT was based on the time interval between entry into the cecum and the capsule exit from the body. Serial plain abdominal films were used to assess the movement of ROM. Correlation of the WMC’s colonic transit with ROMs expelled on day 2/day 5 was $r=0.74/r=0.69$ in the constipated participants, and $r=0.70/r=0.40$ in the control group, respectively. This study did not report whether or not the results were interpreted in a blinded fashion, and there was no discussion of how the diagnostic information was used in the management of the condition.

A 2013 comparative effectiveness review by the AHRQ identified five studies comparing WMC and ROM for diagnosing slow-transit constipation. Although the AHRQ report found that the diagnostic accuracy of WMC and ROM were similar, the strength of evidence (SOE) was determined to be low which indicated “low confidence that the evidence reflects the true effect.” The determination of low SOE was due to several factors, including the retrospective nature of the studies, uncertainty that the studies included the appropriate spectrum of participants, limited follow-up duration of most studies and unclear blinding of outcomes.

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Sangnes (2021) reported on a cross-sectional case-control study that used the WMC to compare GI transit times and contractility parameters in 57 individuals with diabetes (15 with constipation, 42 without) and 26 healthy individuals. Contrary to the traditional view that diabetic constipation is primarily due to slow colonic transit, no differences in gastric, small bowel, colonic, or whole-gut transit were observed between individuals with diabetes and without constipation. However, both diabetes groups demonstrated slower whole-gut transit compared with healthy controls. Constipation symptoms were associated with reduced small bowel motility index but not with colonic transit or colonic contractility, suggesting that mechanisms other than isolated colonic delay, such as small bowel dysfunction or anorectal disorders, may contribute to symptom generation. Limitations include the single-center tertiary referral design and predominance of type 1 diabetes (T1D), limiting generalizability. The constipation subgroup was small, increasing risk of type II error. The cross-sectional design precludes causal inference, and potential confounders such as psychiatric comorbidity and medication effects could not be fully controlled. The WMC measures pressure from a single floating sensor and may have limited sensitivity for detecting subtle contractility abnormalities compared with catheter-based manometry.

WMC for the Evaluation of Suspected Upper and Lower Gastrointestinal (GI) Motility Disorders

Several retrospective studies have been published investigating the use of WMC for the evaluation of suspected upper and lower GI motility disorders. A retrospective study by Rao and colleagues (2011) evaluated the diagnostic utility of the WMC, a noninvasive test that measures transit through the stomach, small intestine, and colon, in 86 individuals with chronic symptoms of suspected gastrointestinal dysmotility and previously normal endoscopic and imaging studies. Individuals were grouped by predominant upper GI (n=36) or lower GI (n=50) symptoms and compared with conventional motility tests such as GES and ROM studies. The WMC confirmed the suspected diagnosis in about 58% of individuals overall and provided new diagnostic information in approximately 50% of individuals, often identifying generalized motility disorders affecting more than one region of the gut. Device agreement with conventional testing was good, and test results led to changes in management in 30% of individuals with lower gastrointestinal symptoms and 50% of those with upper GI symptoms. Limitations include the retrospective design, potential referral bias from a tertiary care center with more severe or refractory cases, lack of simultaneous testing between modalities, and possible conflicts of interest, as one investigator had a financial relationship with the device manufacturer. These factors may limit generalizability and introduce bias, and prospective studies are needed to better define the clinical impact of this technology.

Kuo and colleagues (2011) evaluated the WMC in a retrospective study of 83 participants with suspected gastroparesis, intestinal dysmotility, or slow transit constipation. Databases at 2 referral centers for GI motility were accessed. WMC transits were analyzed and 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. Compared to conventional tests, WMC showed discordance in 38% and provided new diagnoses in 53%. Wireless motility testing reportedly influenced clinical management in 65 participants (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 radiopaque colon marker

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tests (68%). A limitation of this study was that all participants were from two academic centers specializing in managing severe dysmotility syndromes and would therefore differ from a representative community sample. Also, this retrospective investigation involved analyses of preexisting databases and data recording was not standardized, therefore reporting of a lack of a specific symptom or test result may not be the equivalent of symptom absence or non-performance of the test.

Arora and colleagues (2015) performed a single center retrospective chart review of 161 individuals who underwent WMC testing. WMC testing was abnormal in 109 (67.7%) participants. From the abnormal cases, 17 (15.6%) individuals had isolated delayed gastric emptying, 13 (11.9%) had isolated delayed small bowel transit, and 25 (22.9%) had isolated delayed large bowel transit. Multiregional (upper and lower) dysmotility was diagnosed in 54 (49.5%) cases. Of note, the presence or absence of various individually reported symptoms by history did not predict an abnormal study. The authors concluded that “wireless motility capsule can be a useful diagnostic test in patients with suspected multiregional GI dysmotility.” However, they also reported that a limitation of the study was that they “did not attempt to assess if the results of the wireless motility capsule study changed the patients’ outcome or management as the information needed was difficult to obtain in our settings and may be unreliable.”

A retrospective chart review of 100 people with diabetes who had undergone WMC testing at a single institution between the years 2010 to 2015 was performed by Rouphael and colleagues (2017). Of the original 103 participants, 3 were excluded due to either a retained capsule (n=1) or missing data secondary to device failure (n=2). A total of 72% of participants had abnormal WMC results, of which 40% (n=29) had multiregional dysmotility with 6.9% (n=5) having delayed transit in all 3 GI tract segments. Information related to subsequent clinical management post testing was available for 47 subjects. The remaining 53 (53%) participants were excluded from the analysis due to loss to follow-up or incomplete information related to treatment change or response to therapy. Of the 47 participants, WMC testing was abnormal in 70% (n=33) and treatment changes were made in 73% (n=24) of those with gut dysmotility. Limitations of this study included the retrospective nature of the analysis and small sample size.

Rodriguez and colleagues (2021) reported on a prospective series in 57 children age 8 to 18 years who underwent WMC evaluation of upper or lower GI symptoms. A total of 34 individuals also underwent a nuclear medicine gastric emptying study (NMGET) and 21 underwent a colonic radiopaque marker (CROM) transit study. The overall agreement between WMC and NMGET tests was 70%. In 8 individuals, there was an abnormal gastric residency time (GRT) with WMC and a normal NMGET, and GRT was normal in 2 individuals who had an abnormal NMGET. There was an overall agreement of 81% between WMC and CROM studies. A total of 4 individuals had an abnormal CROM study and a normal CTT with WMC, and 1 individual had an abnormal CTT with WMC and a normal CROM. Capsule prolonged retention (beyond 5 days) occurred in 9 individuals; 2 weeks after the study, all of the capsules had been expelled. The study did not evaluate the ability of the WMC to predict health outcomes and there was a lack of controls.

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Garg (2025) reported on a large retrospective, single-center cohort study that analyzed 475 adults with T1D and type 2 diabetes (T2D) who underwent WMC testing to characterize the prevalence and patterns of GI transit abnormalities. Overall, 75.8% exhibited delayed transit in at least 1 region, with delayed gastric emptying (58.8%) being the most common abnormality. T1D was associated with longer diabetes duration, higher HbA1c, greater microvascular complications (neuropathy, retinopathy, nephropathy), higher transplant rates, and a higher prevalence of delayed gastric emptying compared with T2D, while T2D demonstrated relatively longer CTTs. Higher body mass index (BMI) was inversely associated with small bowel and colonic delay, and correlations between HbA1c and transit measures were weak. Mortality appeared higher in T1D on crude analysis but did not differ significantly after time-adjusted Kaplan-Meier analysis. Limitations include the retrospective design, single tertiary referral center population, and referral bias toward individuals already suspected of dysmotility, limiting generalizability. Symptom severity was not correlated with WMC findings, and the observational design precludes causal inference between glycemic control, microvascular complications, and transit abnormalities. Medication effects, including GLP-1 receptor agonists, were not controlled prospectively. Additionally, WMC measures transit of an indigestible capsule rather than physiologic meal emptying, and mechanistic data were limited. Prospective, controlled studies are needed to better define predictors and clinical implications of motility disorders in diabetes.

In a prospective, multicenter comparative cohort study, Kuo (2025), evaluated the performance of the Atmo Capsule, a novel gas-sensing WMC, against the discontinued SmartPill Capsule for measuring GET and CTT in 213 adults with confirmed or suspected GI motility disorders. Strong correlations were observed between devices for GET ($r=0.74$) and CTT ($r=0.69$), with Bland-Altman analyses showing clinically acceptable agreement and small bias relative to established delay thresholds. Diagnostic agreement for delayed GET and CTT was high, with overall accuracy of approximately 84% for both measures. The Atmo Capsule also demonstrated longer battery life, resulting in higher rates of confirmed body exit. No serious device-related adverse events occurred, though capsule retention was reported in a minority of cases. Limitations include a limited demographic diversity (predominantly white, female participants) limiting demographic generalizability; exclusion of rapid transit analysis due to low event frequency; and data loss from device or protocol deviations reducing evaluable samples for certain endpoints. Transit thresholds were derived from prior literature rather than outcome-based validation within this study, and the reference comparator (SmartPill) itself measures emptying of a nondigestible capsule rather than a physiologic meal. Funding and advisory relationships with the device manufacturer introduce potential bias. The need for broader validation across more diverse populations and clinical contexts exists.

In a letter to the editor, Camilleri (2025) responded to the Kuo study questioning the clinical relevance of capsule-derived GETs, arguing that WMC and Atmo capsules measure the emptying of an indigestible solid via the migrating motor complex rather than postprandial emptying of digestible food, which is typically assessed by scintigraphy. The author notes that many healthy individuals can have GETs exceeding the 5-hour cutoff when measured by capsule methods and suggests that this may overestimate delayed emptying relative to physiologic solid-meal emptying.

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In summary, optimal methods with large normative values and demonstrated reproducibility >80% are needed to appraise gastric emptying of solid food in clinical practice. The capsule methods may not be optimal for the measurement of gastric emptying of solid food, which is the clinically relevant issue.

This technical assessment evaluated the ability of the Atmo WMC to quantify gastric contractility using onboard accelerometry in 91 healthy controls and 182 individuals with suspected dysmotility (Hasler, 2026). Following standardized ingestion and Fast Fourier transformation of accelerometer data, the capsule reliably detected physiologic 3 cycles-per-minute gastric contraction frequencies across groups. While contraction frequency did not differ between participants with normal and delayed gastric emptying, contraction amplitudes were significantly lower in those with delayed emptying, suggesting impaired contractile strength rather than altered rhythm. The findings support the technical feasibility of accelerometry to characterize gastric motor profiles and distinguish normal from pathological patterns. Limitations include lack of direct validation against gold-standard measures of gastric contractility such as high-resolution antroduodenal manometry or dynamic MRI, absence of correlation with traditional pressure (mmHg) or luminal deformation metrics, and reliance on arbitrary amplitude units. Participant groups were not age- or sex-matched, and delayed gastric emptying classification was based solely on capsule-derived criteria rather than scintigraphy. The device cannot assess contractile propagation because it is not anatomically fixed, and the study design was observational without longitudinal outcome correlation. Additionally, funding and advisory relationships with the device manufacturer may introduce potential bias. Overall, the study supports technical feasibility while highlighting the need for prospective validation and comparative studies.

In a prospective, multicenter study, Thwaites (2022) compared a novel gas-sensing WMC with the validated WMC in healthy adults to determine accuracy and reproducibility in identifying key GI landmarks and regional transit times. Tandem ingestion demonstrated excellent interobserver agreement for gastroduodenal and ileocecal junction identification with both devices, and regional as well as whole-gut transit times showed strong correlation and minimal bias on Bland-Altman analysis. Median transit times differed only slightly between devices, and tandem ingestion of two gas-sensing capsules showed similar coefficients of variation, suggesting that observed differences likely reflect physiological variability rather than measurement error. Both capsules were well tolerated, with low rates of mild adverse effects and no retentions. Limitations include the relatively small cohort size and restriction to healthy individuals, limiting generalizability to populations with GI disease. Although agreement was strong, identification of landmarks with the WMC failed in a notable minority of cases due to signal loss or pH interpretation challenges. Some technical failures occurred with the gas-sensing capsule (for example, battery or cloud transmission issues). Transit comparisons were not validated against external reference standards such as scintigraphy within this study, and physiological variability in capsule passage complicates interpretation of limits of agreement. Further evaluation in individuals with dysmotility is needed to confirm clinical applicability.

WMCs, including SmartPill Motility Testing System, MotiliCap, and Atmo Gas Capsule System, are not clinically appropriate for evaluating suspected gastric or intestinal motility disorders. They are considered investigational because studies have not shown that they improve health outcomes or guide care better than standard tests. Research shows variable agreement with established tests such as GES

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or radiopaque marker (ROM) studies. Many studies were small, had limited follow up, or did not show that capsule testing improved treatment decisions.

Supplemental Information/Definitions

Current medical society guidance, including American College of Gastroenterology (ACG) and American Gastroenterological Association (AGA) recommend standardized 4-hour solid-meal scintigraphy as the diagnostic reference standard for gastroparesis.

The AGA clinical practice guidelines on *The Management of Gastroparesis* (Staller, 2025) do not include any references to WMC. The guideline emphasizes that diagnosis should be based on a standardized 4-hour gastric emptying study rather than shorter-duration testing, and recommends initial pharmacologic therapy with metoclopramide or erythromycin, with other agents considered through shared decision making based on symptom profile and risk tolerance. For medically refractory disease, the panel suggests selective rather than routine use of procedural interventions such as gastric per-oral endoscopic pyloromyotomy (G-POEM) or gastric electrical stimulation, and identifies surgical pyloric interventions as an area with insufficient evidence to support a recommendation.

According to the ACG (Camilleri, 2022) guidelines for gastroparesis, gastroparesis is defined as having symptoms of gastric retention with objectively delayed gastric emptying in the absence of mechanical obstruction and recommends 4-hour solid-meal scintigraphy as the diagnostic standard, with WMC and stable isotope breath testing as acceptable alternatives in selected cases. Management emphasizes dietary modification (small-particle, low-fat diet), cautious use of prokinetics such as metoclopramide and domperidone (where available), limited roles for antiemetics and central neuromodulators, and selective consideration of interventions including gastric electrical stimulation and pylorus-directed therapies such as G-POEM for refractory cases. Across diagnostic and therapeutic domains, many recommendations are conditional with low or very low certainty of evidence, reflecting heterogeneous study designs, limited randomized trials, modest symptom physiology correlations, variability in testing protocols, and evolving technologies; the guideline highlights substantial knowledge gaps and the need for high-quality, long-term comparative effectiveness studies. WMC had a recommendation that stated “WMC testing may be an alternative to the SGE assessment for the evaluation of GP in patients with upper GI symptoms (conditional recommendation, low quality of evidence).”

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Websites for Additional Information

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Policy History

Original Effective Date: 06/17/2015

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06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. New policy.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018	Medical Policy Committee review

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06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Title changed from Ingestible pH and Pressure Capsule to Wireless Capsule for the Evaluation of Suspected Gastric and Intestinal Motility Disorders. Coverage changed to “Based on review of available data, the Company considers a wireless capsule (SmartPill Motility Testing System) for evaluation of all conditions including, but not limited to the following to be investigational: • Suspected gastric motility disorders (e.g., gastroparesis); or • Suspected intestinal motility disorders (e.g., constipation).”
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/07/2025	Medical Policy Committee review
08/13/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2026	Medical Policy Committee review
08/12/2026	Medical Policy Implementation Committee review
08/20/2026	Medical Quality Management Committee approval. Coverage eligibility unchanged. Title changed from “Wireless Capsule for the Evaluation of Suspected Gastric and Intestinal Motility Disorders” to “Wireless Capsules for the Evaluation of Suspected Gastric and Intestinal Motility Disorders.” Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2027

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)[‡], copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee

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schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	91112
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company

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recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Louisiana Blue), Louisiana Blue may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Louisiana Blue health plan. This provision does not apply to medications covered under the plan's pharmacy benefit.