Molina Clinical Policy
Wireless Capsule for the Evaluation of Suspected Gastric and Intestinal Motility Disorders
Policy No. 382

Last Approval: 06/10/2026
Next Review Due By: June 2027

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Gastroparesis, also referred to as gastric stasis, is a condition characterized by delayed gastric emptying of solid food from the stomach in the absence of mechanical obstruction. Etiologies may include idiopathic causes, diabetes, certain medications (e.g., narcotics, anticholinergics, antidepressants, dopamine agonists, calcium channel blockers), gastrectomy, and systemic sclerosis (Hayes 2024). Iatrogenic gastroparesis may result from surgical interventions that disrupt the vagus nerve, such as during fundoplication for gastroesophageal reflux disease (GERD), or from intentional vagotomy for peptic ulcer treatment. Non-surgical iatrogenic gastroparesis can be caused by medications that impair gastrointestinal motility, including opioids, anticholinergic, and certain diabetic medications. Gastroparesis is identified in clinical practice through both symptom presentation and documentation of delayed gastric emptying. Common symptoms include nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain (Camilleri et al. 2022). A definitive diagnosis of gastroparesis requires objective evidence of delayed gastric emptying in symptomatic individuals. There are three primary methods used to assess gastric motility: gastric emptying scintigraphy, wireless motility capsule testing, and carbon-13 (13C) breath testing. Among these, scintigraphy with a radiolabeled solid meal at four hours is the gold standard. However, motility capsules and 13C breath tests are recognized as potential alternatives, particularly in settings where scintigraphy is not feasible or accessible.

A **wireless motility capsule** is a nonradioactive, office-based diagnostic tool that measures pressure, temperature, and pH as it moves through the gastrointestinal (GI) tract. This single-use, ingestible device provides an ambulatory assessment of GI transit times, including the stomach, small intestine, and colon. The capsule transmits data via radiofrequency signals to an external receiver worn by the patient, allowing for noninvasive, real-time motility evaluation. Wireless motility capsule testing differs from wireless capsule endoscopy in that it cannot obtain endoscopic visualization of the GI tract (Hayes 2025).

Regulatory Status

Wireless motility capsule systems are regulated by the FDA as Class II medical devices and cleared through the 510(k) premarket notification process under product code NYV (GI motility monitoring systems).

The SmartPill Motility Testing System (Medtronic) received FDA clearance in 2006 under 510(k) number K053547 for the evaluation of delayed gastric emptying in adults with suspected gastroparesis. In 2009, its indications were expanded to include measurement of colonic transit time in patients with chronic constipation. As of June 2023, Medtronic has discontinued the SmartPill system (Jalayeri et al. 2024).

The MotiliCap GI Monitoring System (Anx Robitica) receive FDA clearance in 2025 under 510(k) number K250493 for the measurement of GI transit times in adults with suspected gastroparesis or chronic constipation.

The Atmo Gas Capsule System (Atmo Biosciences) receive FDA clearance in 2025 under 510(k) number K250940 for the measurement of GI transit times in adults with suspected gastroparesis or chronic constipation.

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COVERAGE POLICY

Wireless motility capsule testing (e.g., Atmo, MotiliCap, SmartPill) is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes

DOCUMENTATION REQUIREMENTS: Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

Wireless Motility Capsule for the Evaluation of Suspected Gastroparesis

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Hayes (2024) published a Health Technology Assessment evaluating the safety and effectiveness of wireless capsule endoscopy (WCE), including the SmartPill wireless motility capsule (WMC), for diagnosing and managing gastroparesis and other gastrointestinal (GI) motility disorders. The review incorporated 13 nonrandomized studies involving sample sizes from 21 to 196 participants with suspected or confirmed motility disorders. Although the wireless capsule systems were considered safe, the overall quality of the evidence was rated as very low, and findings were insufficient to conclude its effectiveness compared to standard diagnostic tools such as gastric scintigraphy. Six studies comparing WCE to scintigraphy showed inconsistent agreement, with only one reporting comparable diagnostic accuracy. Four studies suggested WCE findings could influence patient management, but only one directly compared WCE to conventional methods. Three additional studies assessing WCE's clinical utility lacked rigor and offered no reliable evidence that SmartPill data improves patient outcomes. The device is considered safe, with no deaths and only minor complications reported in FDA safety databases. However, contraindications include swallowing disorders, GI obstructions, and implanted electromedical devices. The SmartPill is not approved for pediatric use. Guidelines highlight potential benefits, such as noninvasive multi-regional GI transit assessment, but also cite limitations, including weak outcome data, poor symptom correlation, and less physiological insight than gastric scintigraphy. Hayes concluded that while wireless capsule systems like the SmartPill show promise, their clinical value remains uncertain. The assessment assigned a "potential but unproven benefit" rating due to limited, low-quality evidence supporting diagnostic accuracy and no strong evidence of improved patient management or health outcomes.

Lee et al. (2019) conducted a prospective, multicenter study to compare the diagnostic performance of WMC and gastric emptying scintigraphy (GES) in evaluating gastric emptying among 167 individuals with suspected gastroparesis, including both diabetic (n = 53) and non-diabetic (n = 114) participants. The study, conducted across 10 centers from 2013 to 2016, assessed subjects simultaneously using WMC and GES. Delayed gastric emptying was identified in a significantly higher proportion of individuals by WMC (34.6%) compared to GES (24.5%), with an overall agreement of 75.7% between modalities ($p = .009$). WMC detected a higher rate of delayed gastric emptying among non-diabetic subjects (33.3%) compared to GES (17.1%, $p < 0.001$), whereas among diabetic patients, GES detected a higher proportion of delays (41.7%) than in non-diabetics (17.1%, $p = 0.002$). Severe delays in gastric emptying were also more frequently identified using WMC (13.8%) than GES (6.9%, $p = 0.02$). In contrast, rapid gastric emptying was more often detected by GES (13.8%) than by WMC (3.3%, $p < 0.001$). WMC also identified regional and generalized gastrointestinal transit abnormalities in 61.8% of participants, which GES was unable to detect. WMC demonstrated a higher overall diagnostic yield, particularly in detecting extra-gastric motility abnormalities. These findings suggest that WMC not only improves detection of delayed gastric emptying in specific subgroups but may also enhance clinical assessment by capturing broader motility dysfunction. The authors concluded that differences in diagnostic patterns between diabetic and non-diabetic subjects, along with the unique capabilities of WMC, could have significant implications for the diagnosis and management of patients with suspected gastroparesis.

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Stein et al. (2013) performed a comparative effectiveness review evaluating the diagnostic accuracy of the WMC compared to gastric emptying scintigraphy for diagnosing gastroparesis. Among seven studies evaluating delayed gastric emptying, WMC was found to be comparable to scintigraphy in terms of diagnostic accuracy, assessment of motility, influence on treatment decisions, and impact on resource utilization. The sensitivity of WMC compared to scintigraphy ranged from 59% to 86%, while specificity ranged from 64% to 81%. Although complications such as capsule retention and obstruction are possible, serious adverse events were found to be rare. The capsule is contraindicated in pediatric patients and individuals with a known history of esophageal stricture. Limitations of the review included inconsistencies in reporting the performance of motility testing methods, as well as a potential selection bias. Specifically, many study participants had previously undergone diagnostic testing suggestive of delayed gastric emptying, which may have increased the likelihood of positive findings with WMC and thereby skewed the results. The authors concluded that, although data are insufficient to determine the optimal timing of WMC testing within clinical diagnostic algorithms, the device remains a viable and potentially valuable tool for evaluating gastrointestinal motility disorders.

Wireless Motility Capsule for the Evaluation of Suspected Upper and Lower GI Motility Disorders

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Kuo et al. (2025) conducted a multicenter, comparative, prospective cohort study to assess the performance of the Atmo Capsule, a novel WMC, in comparison to the SmartPill Capsule, a now-discontinued reference standard WMC, for measuring gastric emptying time (GET) and colonic transit time (CTT) in individuals with suspected or confirmed gastrointestinal motility disorders. A total of 213 participants were enrolled from 12 sites, with 209 completing the protocol, which required ingesting both capsules in a randomized sequence. The study cohort was primarily white (89%) and female (89%), with a median age of 41 years and a median body mass index (BMI) of 25 kg/m². The primary outcomes were the detection of delayed GET (defined as ≥ 5 hours) and delayed CTT (defined as ≥ 59 hours). Of those analyzed, 177 had paired GET data and 147 had paired CTT data. The Atmo Capsule demonstrated strong correlation with the SmartPill for both GET ($P < .01$) and CTT ($P < .01$), with measurement discrepancies falling within 10% of the delayed transit thresholds. Delayed GET and CTT were each identified in 38% of participants, with an 84% agreement rate between the two devices. The Atmo Capsule showed a sensitivity of 68% and specificity of 91% for detecting delayed GET, and a sensitivity of 83% and specificity of 85% for detecting delayed CTT. No serious adverse events were reported. The study was limited by a lack of demographic diversity and the inability to assess its accuracy in detecting rapid transit times. Overall, findings indicate that the Atmo Capsule performs comparably to the SmartPill in measuring gastrointestinal transit times, supporting its validity as a diagnostic tool for motility disorders (NCT05718505).

Hayes (2025) published a Health Technology Assessment reviewing the safety and effectiveness of WCE for diagnosing and managing small and large bowel motility disorders. The assessment included eight studies ranging from very poor to fair quality. Three studies reported that WCE results influenced changes in patient management, and one noted symptom relief following those changes; however, the studies did not directly compare WCE with established diagnostic techniques. Only one study included statistical analysis, leaving insufficient evidence to determine WCE's relative accuracy. Therefore, while the low-quality body of evidence supports the safety of WCE, there is insufficient evidence to support the effectiveness of therapy.

Arora et al. (2015) conducted a retrospective chart review to assess the clinical utility and diagnostic yield of WMC testing in individuals presenting with symptoms suggestive of multiregional GI dysmotility. The study reviewed 161 individuals who underwent WMC testing. Abnormal motility findings were observed in 109 patients (67.7%), demonstrating WMC's ability to detect a broad range of motility abnormalities across the GI tract. Of the abnormal results, 17 patients (15.6%) had isolated delayed gastric emptying, 13 (11.9%) had delayed small bowel transit, and 25 (22.9%) had delayed large bowel transit. Multiregional dysmotility; indicating involvement of both upper and lower GI regions, was identified in 54 patients (49.5%). A key limitation of the study was the inability to assess whether WMC results influenced patient management or clinical outcomes. The authors noted that collecting such data retrospectively proved difficult and potentially unreliable, limiting the evaluation of WMC's impact on long-term care decisions. Despite this limitation, the study concluded that WMC is a useful diagnostic tool for providing a comprehensive motility profile of the entire GI tract, offering evidence of regional and multiregional dysmotility.

Kuo et al. (2011) conducted a retrospective study evaluating the WMC in 83 individuals with suspected gastroparesis, intestinal dysmotility, or slow transit constipation. Data were obtained from databases at two referral centers specializing in gastrointestinal motility disorders. Analysis of WMC transit times revealed that 32% of patients had isolated regional

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delays, including 9% in the stomach, 5% in the small intestine, 18% in the colon. An additional 35% exhibited generalized delays, while 32% demonstrated normal transit. Symptom profiles did not vary significantly between those with normal transit, regional delays, or generalized delays. When compared to conventional tests, WMC results differed in 38% of cases and led to new diagnoses in 53% of patients. Wireless motility testing significantly impacted clinical management in 67% of cases, prompting changes such as the initiation of new medications (60%), alternations in nutritional plans (14%), and referrals for surgical evaluation (6%). Furthermore, WMC testing reduced the need for additional testing, including gastric scintigraphy (17%), small bowel barium studies (54%), and radiopaque marker tests for colonic transit (68%). The study had several notable limitations. The patient population was drawn exclusively from two specialized academic centers that primarily manage severe dysmotility, limiting the generalizability of findings to the broader population. Additionally, because the study was retrospective and based on preexisting databases, data collection was not standardized. As a result, the absence of specific symptom reports or diagnostic tests in the records may not truly indicate that the symptom was absent or that the test was not performed, thereby introducing potential inaccuracies in the interpretation of the data.

[2]Rao et al. (2011) performed a retrospective study to assess the diagnostic of WMC in 86 patients with suspected gastrointestinal dysmotility who had previously undergone normal endoscopic or radiologic evaluations. The study aimed to determine whether the WMC could provide clinically useful information compared to conventional motility test (CMT). Subjects were classified into two subgroups based on their predominant symptoms: lower gastrointestinal (LGI, n = 50) and upper gastrointestinal (UGI, n = 36). Clinical suspicion of dysmotility was confirmed in 52% of the LGI group and 66% of the UGI group. The WMC demonstrated good agreement with conventional tests in 76% of the LGI group and 81% in the UGI group. Additionally, the WMC yielded new diagnostic information in 53% of LGI ($p = 0.006$) and 47% of UGI patients ($p = 0.001$). The WMC detected generalized motility disorder in 51% of all subjects and influenced management in 30% of LGI and 88% of UGI patients. The study had several limitations, including its retrospective design, which is subject to inherent bias, and the inclusion of patients with more severe symptoms than typically in routine clinical practice. Moreover, WMC and conventional testing were not performed simultaneously, which may have contributed to discrepancies in results.

Camilleri et al. (2010) assessed the validity of WMC by comparing it to radiopaque marker (ROM) measurements of colonic transit time in a multicenter study involving 180 individuals with self-reported constipation. Participants ingested both the WMC and ROM capsules. CTT comparisons between WMC and ROM were analyzed in 157 subjects, with additional assessment of combined small and large bowel transit in 154 subjects. Among the 157 participants, 59 were identified as having delayed colonic transit based on ROM results. The WMC demonstrated a high overall diagnostic agreement with ROM at 87%, with a positive percent agreement of approximately 80% for delayed transit ($p = 0.01$) and a negative percent agreement of 91% for normal transit ($p = 0.00001$). Statistically significant correlations were observed between WMC and ROM measurements of colonic transit and between WMC and ROM for combined small and large bowel transit times, both with p-values < 0.001. Adverse events were minimal, with two subjects unable to swallow the capsule and isolated cases of abdominal cramping, nausea, and loose stools attributed to the WMC. Potential limitations of using capsule-based methods for measuring gastrointestinal transiting included technical failures, the inability to swallow the capsule, risk of non-passage or obstruction in patients with stricturing disorders, and higher costs relative to the ROM method. The results supported the WMC as a reliable and comprehensive tool for evaluating colonic transit in patients with constipation.

National and Specialty Organizations

The **American College of Gastroenterology (ACG)** published guidelines for the diagnosis and management of gastroparesis in adults, identifying gastric scintigraphy with a solid-phase meal as the gold standard due to its ability to provide direct and quantifiable measurement of gastric emptying. The ACG lists WMC testing as a potential alternative to gastric scintigraphy for the evaluation of gastroparesis in patients with upper GI symptoms. However, the this as a conditional recommendation based on low quality evidence, which the ACG panel assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) process. Overall, gastric scintigraphy remains the preferred diagnostic method, with WMC serving as a supplementary tool that should be interpreted alongside clinical symptoms and other diagnostic data. The diagnostic value of WMC testing for gastroparesis, for the measurement of pan-GI transit and pressure profiles, and for autonomic nervous system dysfunction, remains under investigation (Camilleri et al. 2022).

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The **American Neurogastroenterology and Motility Society (ANMS)** and the **European Society of Neurogastroenterology and Motility (ESNM)** issued a joint position paper regarding the evaluation of gastrointestinal transit. The use of WMC was recommended for assessing gastric emptying, small bowel transit time (SBTT), CTT, and WGTT in patients suspected of having gastroparesis or gastrointestinal dysmotility affecting multiple regions. The WMC was noted for being safe, validated, and free of radiation, making it useful for patients for whom gastric emptying scintigraphy is not feasible, such as pregnant women, breastfeeding women, and children. Both scintigraphy and WMC were identified as valuable for evaluating regional and whole-gut transit in individuals with suspected GI motility issues across different areas. However, the position paper emphasized that further evidence is needed to fully establish the clinical utility and accuracy of WMC testing ([1]Rao et al. 2011).

The **American Gastroenterological Association (AGA)** published a clinical practice update on the management of medically refractory gastroparesis. The authors state that because WMC testing identifies phase III activity front of the migrating motor complex rather than overall gastric emptying. A meal-based test using gastric scintigraphy provides better physiological assessment of gastric emptying, and as a result, it continues to be the recommended first line test (Lacy et al. 2022).

The **National Institute for Health and Care Excellence (NICE)** published guidelines on the assessment of GI motility using wireless capsule testing. The guideline states that while there is evidence of efficacy and no major safety concern, the clinical benefits and patient selection criteria for WMC remain uncertain. The procedure should only be used with special arrangements for clinical governance, consent, and audit or research. Further research should include clear details on patient selection, the diagnostic accuracy on different parts of the GI tract, and clinical benefits (NICE 2014).

SUPPLEMENTAL INFORMATION

Gastric Emptying Scintigraphy: A type of test which uses a radio-labeled meal to measure gastric emptying.

Gastroparesis: A condition where there is delayed gastric emptying and characteristic gastrointestinal symptoms.

Colonic Transit Time: The time between cecal entry of capsule and its exit from the body. Where time of cecal entry is not possible due to poor pH landmark (approximately 5% of cases), small and large bowel transit time is calculated. Measurement of colonic transit time is indicated in patients with chronic constipation to distinguish slow from normal transit constipation.

Whole Gut Transit Time: The combined transit time of gastric emptying time, small and large bowl transit time, and colonic transit time is defined as delayed when greater than 73 hours and rapid transit as less than 10 hours.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

CODING DISCLAIMER: Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

06/10/2026 Policy reviewed. No change to coverage criteria. Added info about the Atmo and MotiliCap systems.

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06/11/2025	Policy reviewed. No changes to coverage criteria. Updated Summary of Medical Evidence and References.
08/14/2024	Policy reviewed. Updated Summary of Medical Evidence and References. IRO Peer Review on July 31, 2024, by a practicing physician board-certified in Internal Medicine, Gastroenterology.
08/09/2023	Policy reviewed, no changes to coverage criteria, updated references.
08/10/2022	Policy reviewed, no changes to coverage criteria, updated references.
08/11/2021	Policy reviewed, no changes to coverage criteria, updated references.
09/16/2020	New policy.

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