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

Last Approval: 08/14/2024
Next Review Due By: August 2025

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 disorder characterized by delayed gastric emptying of solid food in the absence of a mechanical obstruction of the stomach. Gastroparesis can have idiopathic, diabetic, iatrogenic, post-surgical or post-viral etiologies (Parkman et al. 2011). Known causes of iatrogenic gastroparesis include surgical vagal disruption, which may be due to vagal nerve injury (e.g., after fundoplication for GERD), or intentional vagotomy as part of peptic ulcer surgery. Non-surgical iatrogenic gastroparesis can be induced by pharmacological agents such as narcotic opiate analgesics, anticholinergic agents, and some diabetic medications. Gastroparesis is identified in clinical practice through the recognition of the clinical symptoms and documentation of delayed gastric emptying. Symptoms from gastroparesis include nausea, vomiting, early satiety, postprandial fullness, bloating, and upper abdominal pain (Camilleri et al. 2013). The diagnosis of gastroparesis requires objective evidence of clearly delayed gastric emptying in symptomatic patients. There are three tests to objectively demonstrate delayed gastric emptying: scintigraphy, wireless motility capsule (WMC), and breath testing. Gastric emptying scintigraphy of radiolabeled solid test meal at 4 hours is standard for diagnosis of gastroparesis. Wireless capsule motility testing and breath tests with carbon-13 (13C) are alternatives to gastric emptying scintigraphy in assessing delayed gastric emptying.

A **Wireless Motility Capsule** is a nonradioactive, office-based, gastrointestinal (GI) transit testing modality that obtains images and/or measurements of temperature, pressure, and pH as it moves through the GI tract. Ingestion of this non-digestible capsule allows for the measurement of gastric, small bowel, and colonic transit times in an ambulatory setting. The capsule transmits measurements via radio signals to an external recording device.

Regulatory Status

Wireless capsule systems are regulated by the Food and Drug Administration (FDA) as Class II devices and assigned the Product Codes NYV (gastrointestinal motility monitoring system), NEZ (system, imaging, gastrointestinal, wireless, capsule), NSI (system, imaging, esophageal, wireless, capsule), and/or PGD (colon capsule imaging system) (FDA 2009).

An ingestible capsule (SmartPill® GI Monitoring System; Given Imaging) was cleared for marketing by the FDA through the 510(k) process, for evaluation of delayed gastric emptying, or gastroparesis. In 2009, the FDA expanded the use of the SmartPill® to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow- and normal- transit constipation. The SmartPill GI Monitoring System includes a capsule activation device, laptop computer with docking station, and software for data display and analysis (Kloetzer et al. 2010; Medtronic 2016). The SmartPill device is also referred to in this document as a WMC (FDA 2009).

The SmartPill Motility Capsule (Medtronic) is part of the SmartPill motility testing system. The capsule technology is a 13 × 26 millimeter (mm), self-contained electronic device that wirelessly measures gastrointestinal pH, temperature, and pressure. The study is conducted on an outpatient basis, in a physician office, after the patient has discontinued use of all medications that affect the GI tract. The patient ingests the capsule, and a data receiver nearby collects the data transmitted by the capsule. After data collection, the receiver is returned to the physician for downloading and analysis. 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 capsule is usually eliminated in the stool in 24 to 48 hours and passage can be verified by plain radiography. After data collection is complete, the data receiver is returned to the physician for downloading and analysis of the pH, temperature, and pressure data. Gastroparesis is detected based on prolonged gastric transit time, which is detected based on the fall in pH during exposure to stomach acid and subsequent rise in pH upon small bowel entry. Small bowel and large bowel transit times are measured based on changes in pH and temperature (Arora et al. 2015). The capsule is not FDA approved for use in pediatric patients.

COVERAGE POLICY

This policy addresses a wireless motility capsule (WMC) for the evaluation of suspected gastric and intestinal motility disorders (SmartPill™ Motility Testing System [Medtronic, Minneapolis, MN]). The WMC is an orally ingested, nondigestible, data-recording device that enables the simultaneous assessment of regional and whole gut transit to assesses gastroparesis or delayed gastric emptying.

WMC (SmartPill Motility Testing System) is considered **not medically necessary** for the evaluation of suspected gastric and intestinal motility disorders, as well as all other indications. There is a lack of high-quality peer-reviewed, evidence-based literature to determine that the diagnostic performance and clinical utility surpass conventional means of measuring gastric emptying. Studies evaluating the usefulness of WMC testing in suspected gastric motor disorders have been limited by study design and small sample sizes. Larger, well-designed studies are needed that compare results with use of this device (using an established protocol and cutoff values) with the current standard test. Evaluation of cases with discordant results would be of value. If possible, these studies should be linked to therapeutic decisions and to meaningful clinical 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

A comparative effectiveness review comparing wireless motility capsule (WMC) and gastric emptying scintigraphy for diagnosing gastroparesis by the Agency for Healthcare Research and Quality (AHRQ) reported that the diagnostic accuracy of WMC and gastric emptying scintigraphy were similar; however, the strength of evidence was noted as low which indicates “low confidence that the evidence reflects the true effect” (Stein et al. 2013). The primary limitations contributing to the low strength of the evidence includes the retrospective nature of the studies, uncertainty that the studies included the appropriate spectrum of participants (participant eligibility criteria and criteria for positive test findings were not clearly pre-specified), limited follow-up duration of most studies, and unclear blinding of outcomes. The review concluded that while WMC appears to be accurate in detection of gastroparesis and slow-transit constipation, and may provide increased diagnostic gain as compared with standard motility testing, the evidence is insufficient to determine whether use of the WMC will improve outcomes of care. In the systematic review:

- The WMC was identified as an effective modality for diagnosing gastric and colonic motility disorders when compared with other tests of gastric and colonic motility; however, the quality of evidence regarding its ability to detect gastroparesis or slow-transit constipation was graded as low.
- Seven studies evaluated diagnosis of gastric emptying delay and found the WMC comparable to scintigraphy for diagnostic accuracy, accuracy of motility assessment, effect on treatment decisions, and effect on resource utilization. Sensitivity of the WMC compared with gastric scintigraphy ranged from 59-86%; specificity ranged from 64% to 81%.
- Capsule retention and obstruction are potential complications, but serious complications are rare.
- They are contraindicated in children and patients with a known history of esophageal stricture.

- The main limitations of the review were inconsistencies in reporting the performance of motility testing modalities. There is also a built-in bias in favor of the WMC as subjects had undergone other testing suggestive of gastric emptying delay, in effect preselecting those individuals most likely to be affirmed with positive findings for wireless mobility capsule study. The authors concluded that data are insufficient to determine the optimal timing of motility capsule testing in diagnostic algorithms, but the WMC constitutes another viable and useful diagnostic modality.

Hasler et al. (2018 & 2008) stated that testing to define delayed gastric emptying is needed to diagnose gastroparesis. Commonly performed methods of gastric emptying testing include scintigraphy and breath testing. The SmartPill WMC system is FDA-approved for evaluating suspected delayed emptying in gastroparesis and functional dyspepsia. The device measures transit in the stomach, small intestine, and colon by detecting characteristic pH transitions; and quantifies pressure waves in each gut region. The gastric emptying times of WMC correlate with scintigraphic measures. Incremental benefits of WMC testing in patients with suspected gastroparesis include delineation of pressure abnormalities, and small intestinal and colonic transit delays. The authors noted that acceptance of trial data confirming usefulness of WMC testing in suspected gastric motor disorders has been hindered by small sample sizes and design limitations. It was concluded that ongoing multi-center studies will validate the utility of WMC methods in patients with suspected gastroparesis and other upper GI motor disorders.

Several recent studies have compared simultaneous WMC and gastric emptying scintigraphy in individuals with suspected gastroparesis.

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

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

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

Studies evaluating the usefulness of WMC testing in suspected gastric motor disorders have been limited by study design and the small sample sizes of some studies. Larger, well-designed studies are required that compare results with use of this device with the current standard test.

The 2013 Agency for Healthcare Research and Quality (AHRQ) review found that there was a lack of evidence on the clinical utility of testing with the ingestible capsule. The review found 3 studies, including 1 abstract, on management changes following use of the SmartPill. Kuo et al. (2011) and Rao et al. (2011), reported that WMC testing resulted in a new diagnosis in about 50% of patients. Due to the limited data, AHRQ reviewers considered the evidence insufficient to determine the impact of testing results of the ingestible capsule on treatment and management decisions (Stein et al. 2013). Retrospective studies published evaluating WMC for suspected upper and lower GI motility disorders include:

Rao et al. (2011) evaluated the WMC in 86 patients with suspected upper and lower gastrointestinal dysmotility. Study participants were required to have symptoms of dysmotility (abdominal pain, nausea, vomiting, bloating, fullness after meals, constipation, straining, or feeling of incomplete evacuation) and normal endoscopic/radiologic evaluations. The diagnostic utility of the WMC was retrospectively assessed by examining device agreement and new information

compared with conventional motility tests. Study subjects were classified into two subgroups based on major symptom(s): lower GI (n=50) and upper GI (n=36). Clinical suspicion was confirmed in 52% and 66% of study subjects, respectively, and the authors stated there was good device agreement between the WMC and conventional tests in 76% and 81% in the lower GI and upper GI groups, respectively. There was new diagnostic information with the wireless motility test in 53% of the lower GI (p=0.006) and 47% of the upper GI group (p=0.001). The WMC detected generalized motility disorder in 44 (51%) subjects and influenced management in 30% of lower GI and 88% of upper GI subjects. Study limitations noted by the authors included potential bias of a retrospective study, the inclusion of subjects with more severe symptoms than are typically seen at a tertiary care center, and the tests were not conducted simultaneously which could result in discrepancy between the test results.

Kuo et al. (2011) evaluated the WMC in a retrospective study of 83 subjects with suspected gastroparesis, intestinal dysmotility, or slow transit constipation. Databases at two referral centers for gastrointestinal 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% of subjects. Wireless motility testing influenced clinical management in 65 subjects (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 tests (68%). A limitation of this study was that all subjects were from two academic centers specializing in managing severe dysmotility syndromes and would therefore differ from a representative community sample. Also, of note, 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 et al. (2015) conducted a single center retrospective chart review of 161 individuals who underwent WMC testing. WMC testing was abnormal in 109 (67.7%) subjects. 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 study concluded that WMC can be a useful diagnostic test in patients with suspected multiregional GI dysmotility. However, the authors also reported that a limitation of the study was that they 'did not attempt to assess if the results of the WMC study changed the patients' outcome or management as the information needed was difficult to obtain in our settings and may be unreliable.'

Wireless Motility Capsule for the Evaluation of Suspected Chronic Constipation

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

AHRQ presented results in a comparative effectiveness review identifying 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 was determined to be low which indicated 'low confidence that the evidence reflects the true effect.' The determination of low strength of evidence 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 (Stein et al. 2013).

Camilleri et al. (2010) compared the WMC to ROM measurements of colon transit time in a study of 180 individuals with symptoms of self-reported constipation enrolling in the multicenter trial. The study participants ingested both the WMC and ROM. After exclusions and missing data, the assessment of colonic transit time was based on comparisons between WMC and ROM in 157 subjects, and comparison between small and large bowel transit times by WMC and ROM in 154 subjects. Study results indicated that 59 of 157 subjects 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 small and large bowel transit times. Estimates of colonic transit times and small and large bowel transit times 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 subjects 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.'

Rao et al. (2009) compared transit times in both constipated (n=78) and healthy subjects (n=87) measured simultaneously with the WMC and ROM. The WMC estimated the small and large bowel transit times based on pH changes as the capsule entered the duodenum (increase in pH) and then passed into the cecum (decrease in pH). The colonic transit time 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 was r=0.74/r=0.69 in the constipated subjects, and r=0.70/r=0.40 in the control group, respectively. This study did not report whether 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.

In 2017, Hayes published a Health Technology Assessment of *Wireless Capsule Systems for the Diagnosis of Gastroparesis and Monitoring of Gastrointestinal (GI) Motility*. A literature review of 13 nonrandomized studies (3 cross-sectional comparative studies, 7 prospective case-control studies, and 3 retrospective pretest/posttest studies) as eligible for inclusion was conducted. Sample sizes ranged from 21 to 196 patients with known or suspected GI motility disorders. Outcome measures included sensitivity, specificity, and accuracy of motility disorder detection.

- While 13 studies were evaluated, the report noted that "these studies provide limited evidence concerning the accuracy of the wireless capsule systems and no reliable evidence that use of these systems improves patient outcomes." Five studies evaluated the use of the SmartPill WMC to detect gastroparesis; however, these studies, "provided limited evidence of the accuracy of WMC."
- Six studies reviewed the SmartPill WMC for the detection of delayed colonic transit. Studies compared WMC to conventional techniques (e.g., radiopaque markers), and although agreement between WMC and these techniques was generally good, "the reported measures of test agreement are not precise indicators of the accuracy of WMC relative to conventional testing methods."
- Three studies evaluated the clinical utility of WMC testing to improve patient management. Due to their poor quality (retrospective, no follow-up), these studies provided no reliable evidence that information from WMC testing improves patient management.

The Health Technology Assessment noted that the overall quality of evidence was determined to be low due to individual study limitations, including lack of randomization, small study size, retrospective analysis, lack of follow-up, and incomplete testing of enrolled patients. The Hayes review concluded that additional studies are needed to determine the accuracy of wireless capsule systems relative to standard testing for the detection of GI motility disorders. "Additional studies are also needed to demonstrate that the information obtained with wireless capsule systems can be used to improve the management and health outcomes of patients who have GI motility disorders." The Health Technology Assessment concluded that 'the clinical value of wireless capsule systems for the diagnosis and management of patients with GI motility disorders is promising but questions remain regarding the accuracy and optimal role in management of these disorders relative to standard tests.' Hayes assigned a potential but unproven benefit rating for assessment of GI motility with the SmartPill WMC system in adult patients without contraindications to use. This rating is reflective of the 'limited, low-quality evidence that the SmartPill system may be as accurate as conventional methods for detection of gastroparesis and delayed motility but no reliable evidence that information from the SmartPill system improves patient management or health outcomes.'

A 2023 Health Technology Assessment reviewed the safety and effectiveness of wireless capsule endoscopy (WCE) for diagnosing and managing small and large bowel motility disorders. The assessment included eight studies of very poor to fair quality. The evidence indicates that WCE can detect abnormalities related to constipation severity, lead to changes in management recommendations, and provide symptom relief for some patients following these 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 (Hayes 2023).

National and Specialty Organizations

The American Gastroenterological Association published the 2013 guidelines on gastroparesis diagnosis and treatment indicated WMC testing requires validation before it can be considered as an alternative to scintigraphy for diagnosing gastroparesis. Gastric emptying scintigraphy was considered the best-accepted method to assess for delays in gastric emptying (Camilleri et al. 2013).

The American College of Gastroenterology states that gastric emptying scintigraphy of a solid phase meal is the diagnostic standard for gastroparesis for its ability to provide a noninvasive, direct, and quantifiable measure of gastric emptying (Camilleri 2013). While scintigraphic protocols vary among providers, the most reliable measure is gastric retention of solids at 4 hours, as studies of shorter duration or based on a liquid challenge are less sensitive for diagnosing gastroparesis. It is noted that the diagnostic value of WMC and breath testing as alternatives to gastric emptying scintigraphy is controversial. Further validation of wireless motility testing and breath testing are recommended before considering them as alternatives to gastric emptying scintigraphy.

The American and European Neurogastroenterology and Motility Societies issued a position paper (2011) on the evaluation gastrointestinal transit and recommended by consensus the WMC for assessing gastric emptying, and small bowel, colonic, and whole-gut transit times in patients with suspected gastroparesis or gastrointestinal dysmotility in multiple regions. The position paper noted, however, that the clinical utility of identifying delays in small bowel transit times is unknown (Rao et al. 2011).

- WMCs and breath tests are safe, validated, and radiation-free alternatives that offer advantages to individuals in whom gastric emptying scintigraphy is contraindicated or not feasible, such as pregnant women, breast-feeding women, and children.
- Scintigraphy and WMC can assess regional and whole-gut transit and offer value for individuals with suspected alterations of gastrointestinal motility in multiple regions.
- Recommendations for the WMC are limited due to insufficient supporting evidence to fully establish the clinical utility or accuracy of the SmartPill.

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. There was a good correlation between scintigraphic whole gut transit time and the WMC. Constipated patients have been shown in a prospective study to have slower whole gut transit time.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Code

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

APPROVAL HISTORY

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.

REFERENCES

1. Arora Z, Parungao JM, Lopez R, et al. Clinical utility of wireless motility capsule in patients with suspected multiregional gastrointestinal dysmotility. Dig Dis Sci. 2015; 60(5):1350-1357. doi: 10.1007/s10620-014-3431-9.
2. Camilleri M, Parkman HP, Shafi MA, et al. American College of Gastroenterology (AGA) clinical guideline: Management of gastroparesis. Am J Gastroenterol. 2013;108(1):18-38. doi:10.1038/ajg.2012.373.
3. Camilleri M, Thorne NK, Ringel Y, et al. Wireless pH-motility capsule for colonic transit: Prospective comparison with radiopaque markers in chronic constipation. Neurogastroenterol Motil. 2010;22(8):874-882. doi: 10.1111/j.1365-2982.2010.01517.
4. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: Management of gastroparesis. Am J Gastroenterol. 2013;108(1):18-37.
5. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database (no National Coverage Determination identified).
6. Hayes. Health technology assessment: Wireless capsule systems for diagnosis of gastroparesis and monitoring of gastrointestinal motility. Published September 21, 2017. Updated November 27, 2023. https://evidence.hayesinc.com/.
7. Hayes. Health technology assessment: Wireless capsule systems for diagnosis of small and large bowel motility disorders. Published September 26, 2023. https://evidence.hayesinc.com/.
8. Hasler WL, May KP, Wilson LA, et al. Relating gastric scintigraphy and symptoms to mobility capsule transit and pressure findings in suspected gastroparesis. Neurogastroenterol Motil. 2018 Feb;30(2):10.1111/nmo.13196. doi: 10.1111/nmo.13196.
9. Hasler WL, Coleski R, Chey WD, et al. Differences in intragastric pH in diabetic vs. idiopathic gastroparesis: relation to degree of gastric retention. Am J Physiol Gastrointest Liver Physiol. 2008 Jun;294(6):G1384-91. doi: 10.1152/ajpgi.00023.2008.
10. Kloetzer L, Chey W, McCallum R, et al. Motility of the antroduodenum in healthy and gastroparetics characterized by wireless motility capsule. Neurogastroenterol Motil. 2010;22(5):527-533. doi: 10.1111/j.1365-2982.2010.01468.
11. Kuo B, Maneerattanaporn M, Lee AA, et al. Generalized transit delay on wireless motility capsule testing in patients with clinical suspicion of gastroparesis, small intestinal dysmotility, or slow transit constipation. Dig Dis Sci. 2011; 56(10):2928-2938. doi: 10.1007/s10620-011-1751-6.
12. Lee AA, Rao S, Nguyen LA et al. Validation of diagnostic and performance characteristics of the wireless motility capsule in patients with suspected gastroparesis. Clin Gastroenterol Hepatol. 2019 Aug;17(9):1770-1779.e2. doi: 10.1016/j.cgh.2018.11.063.
13. Medtronic. SmartPill motility testing system [product brochure]. https://www.medtronic.com/covidien/en-us/products/motility-testing.html.
14. Parkman HP, Hasler WL, Fisher RS, American Gastroenterological Association (AGA). American Gastroenterological Association medical position statement: Diagnosis and treatment of gastroparesis. Gastroenterology 2004 Nov;127(5):1589-91. doi: 10.1053/j.gastro.2004.09.054.
15. Parkman HP, Hasler WL, Fisher RS. American Gastroenterological Association (AGA) technical review on the diagnosis and treatment of gastroparesis. Gastroenterology. 2004;127(5):1592-622. https://doi.org/10.1053/j.gastro.2004.09.055.
16. Parkman HP. Assessment of gastric emptying and small-bowel motility: scintigraphy, breath tests, manometry, and SmartPill. Gastrointest Endosc Clin N Am. 2009; 19(1):49-55, vi.
17. Rao SS, Camilleri M, Hasler WL, American and European Neurogastroenterology and Motility Societies, et al. Evaluation of gastrointestinal transit in clinical practice: Position paper of the American and European Neurogastroenterology and Motility Societies. Neurogastroenterol Motil. 2011;23(1):8-23. doi: 10.1111/j.1365-2982.2010.01612.
18. Rao SS, Kuo B, McCallum RW, et al. Investigation of colonic and whole-gut transit with wireless motility capsule and radiopaque markers in constipation. Clin Gastroenterol Hepatol. 2009 May;7(5):537-44. doi: 10.1016/j.cgh.2009.01.017.
19. Rao SS, Mysore K, Attaluri A, Valestin J. Diagnostic utility of wireless motility capsule in gastrointestinal dysmotility. J Clin Gastroenterol. 2011 Sep;45(8):684-90. doi: 10.1097/MCG.0b013e3181ff0122.
20. Sangnes DA, Søfteland E, Bekkelund M et al. Wireless motility capsule compared with scintigraphy in the assessment of diabetic gastroparesis. Neurogastroenterol Motil. doi: 10.1111/nmo.13771.
21. Stein E, Berger Z, Hutfless S, Shah L, et al. Wireless Motility Capsule Versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness Review [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2013 May. Report No.: 13-EHC060-EF. PMID: 23785726.
22. United States Food and Drug Administration (FDA). 510(k) premarket notification database: SmartPill GI monitoring system (version 2.0). FDA. Published October 30, 2009. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.