

# Clinical Policy: Wireless Motility Capsule

Reference Number: PA.CP.MP.143 Effective Date: 09/01/2018 Date of Last Revision: 09/23 Coding Implications <u>Revision Log</u>

## Description

The wireless motility capsule (WMC) assesses gastroparesis or delayed gastric emptying.<sup>1,2</sup> The WMC is an orally ingested, nondigestible, data-recording device that enables the simultaneous assessment of regional and whole gut transit.<sup>1-3</sup>

#### **Policy/Criteria**

It is the policy of PA Health & Wellness (PHW)<sup>®</sup> that wireless motility capsule (WMC) is **not medically necessary** for the evaluation of suspected gastric and intestinal motility disorders, as well as all other indications. There is a paucity of peer-reviewed, evidence-based literature to determine that the diagnostic performance and clinical utility surpass conventional means of measuring gastric emptying.

#### Background

The U.S. Food and Drug Administration approved wireless motility capsule (WMC) for the evaluation of patients with suspected gastroparesis, even though there is no sign of a blockage.<sup>1-2</sup> The WMC, which is a 26 x 13 mm size capsule with a battery life of five days, is also proposed to evaluate colonic transit time in patients with chronic idiopathic constipation.<sup>2</sup> Additionally, the WMC is noted to continuously measure the temperature, pH, and pressure of its surrounding environment while traveling through the gastrointestinal tract, via gut peristalsis, until exiting the body through the anus.<sup>4,5</sup>

After eating a standard meal, the member/enrollee swallows the capsule and wears a small monitor that makes telemetry recordings. The established cutoff point for gastric emptying time is 300 minutes. Gastric emptying of the WMC seems to occur with the Phase III migrating motor complex, signifying completion of postprandial phase and return of the fasting state. It assesses small bowel transit time by a sharp increase in pH on entry into duodenum and by a fall in pH at the ileocecal junction. However, in 15% of patients, this pH drop is not observed, and this may be related to the ileocecal valve incompetence.<sup>5</sup> An example of a wireless GI motility monitoring system is the SmartPill<sup>®</sup> GI monitoring system 2.0.

Advantages of the WMC include that it is wireless and painless and contains no radiation.<sup>3</sup> Disadvantages of the capsule include failure to capture data that would require repeat testing, and delay or total failure to pass the capsule, requiring serial x-rays to document passage or endoscopic or surgical removal. Another disadvantage is that it should not be used in patients with a possible stricture, altered anatomy, or severe pyloric stenosis.<sup>7</sup> Patients ideally should be able to tolerate not using proton pump inhibitors and histamine-2 blockers before testing.<sup>7</sup>

## Agency for Healthcare Research and Quality (AHRQ)<sup>6</sup>

WMC is comparable in accuracy to current modalities in use for detection of slow-transit constipation and gastric emptying delay and is therefore another viable diagnostic modality. Little data are available to determine the optimal timing of WMC for diagnostic algorithms.

## **CLINICAL POLICY** Wireless Motility Capsule



## American College of Gastroenterology<sup>8</sup>

Scintigraphic gastric emptying of solids is the standard for the evaluation of gastric emptying and the diagnosis of gastroparesis. Alternative approaches for assessment of gastric emptying include WMC testing and 13C-spirulina breath testing. (Conditional recommendation, low quality of evidence).

#### American and European Neurogastroenterology and Motility Societies

Tests of gastrointestinal transit are available and useful in the evaluation of patients with symptoms suggestive of gastrointestinal dysmotility since they can provide objective diagnosis and a rational approach to patient management.<sup>9</sup>

Studies note that WMC is comparable in accuracy to current modalities in use for detection of slow-transit constipation and gastric emptying delay and is therefore another viable diagnostic modality. However, little data are available to determine the optimal timing of this device for diagnostic algorithms.<sup>10</sup>

Other studies have noted that the sensitivity and specificity of the WMC is comparable to radiopaque marker test and scintigraphic gastric emptying.<sup>12</sup> WMC is well tolerated, has good compliance, and avoids the risk of radiation exposure, however, it is not clear if it provides added clinical value in most patients.<sup>5,7,12</sup>

#### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT<sup>®</sup>). CPT<sup>®</sup> is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT <sup>®</sup> Codes	Description
91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report

HCPCS Codes	Description
N/A	

#### **ICD-10-CM Diagnosis Codes Related to Procedure**

ICD-10-CM	Description
Code	
K31.84	Gastroparesis
K59.01	Slow transit constipation
K59.04	Chronic idiopathic constipation



Reviews, Revisions, and Approvals	Date	Approval Date
New payment policy developed.	04/17	04/17
References reviewed and updated.	02/18	03/18
Annual review, no changes.	10/19	
Revised statement in background from the American College of Gastroenterology. References reviewed and updated. Specialist	10/2020	12/2020
reviewed.		
Added language to the American College of Gastroenterology statement in background. References reviewed and updated. Replaced "member" with "member/enrollee" in all instances.	7/2021	
Annual review. Changed "review date" in the header to "date of last revision" and "date" in the revision log header to "revision date." Criteria section updated with wording for abbreviation. Background updated with no impact on criteria. References reviewed and updated. Specialist reviewed.	2/21/2023	
Annual review. Background updated with no impact on criteria. References reviewed and updated. External specialist review.	09/2023	

### References

- Rao SS, Camilleri M, Hasler WL, 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 to 23. doi:10.1111/j.1365-2982.2010.01612.x
- U.S. Food and Drug Administration 510(k) Premarket Notification Database. SmartPill GI Monitoring System. Version 2.0 Summary of Safety and Effectiveness No. K092342. Silver Spring, MD: FDA. July 29, 2009.

http://www.accessdata.fda.gov/cdrh\_docs/pdf9/K092342.pdf. Accessed August 19, 2022.

- Local coverage determination: Wireless Gastrointestinal Motility Monitoring System (L33455). Centers for Medicare and Medicaid Services Web site. <u>http://www.cms.hhs.gov/mcd/search.asp</u>. Published October 01, 2015 (revised September 09, 2021. Accessed August 16, 2022.
- 4. Arora Z, Parungao JM, Lopez R, Heinlein C, Santisi J, Birgisson S. Clinical utility of wireless motility capsule in patients with suspected multiregional gastrointestinal dysmotility. *Dig Dis Sci.* 2015;60(5):1350 to 1357. doi:10.1007/s10620-014-3431-9
- 5. Lembo AJ. Overview of Gastrointestinal Testing. UpToDate. <u>www.uptodate.com</u> Published January 12, 2021. Accessed August 16, 2022.
- 6. Stein E, Burger Z, Hutless S, et al. *Wireless Motility Capsule Versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness Review.* Rockville (MD): Agency for Healthcare Research and Quality (US); May 2013.
- 7. Saad RJ. The Wireless Motility Capsule: a One-Stop Shop for the Evaluation of GI Motility Disorders. *Curr Gastroenterol Rep.* 2016 Mar;18(3):14. doi: 10.1007/s11894-016-0489-x
- 8. Camilleri M, Kuo B, Nguyen L, et al. ACG Clinical Guideline: Gastroparesis. *Am J Gastroenterol*. 2022;117(8):1197 to 1220. doi:10.14309/ajg.00000000001874f

## **CLINICAL POLICY** Wireless Motility Capsule



- 9. Camilleri M, Bharucha AE, di Lorenzo C, et al. American Neurogastroenterology and Motility Society consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice. *Neurogastroenterol Motil*. 2008;20(12):1269 to 1282. doi:10.1111/j.1365-2982.2008.01230.x
- Farmer AD, Wegeberg AL, Brock B, et al. Regional gastrointestinal contractility parameters using the wireless motility capsule: inter-observer reproducibility and influence of age, gender and study country. *Aliment Pharmacol Ther*. 2018 Feb;47(3):391 to 400. doi: 10.1111/apt.14438
- 11. 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; 17(9):1770 to 1779.e2. doi:10.1016/j.cgh.2018.11.063
- 12. Tran K, Brun R, Kuo B. Evaluation of regional and whole gut motility using the wireless motility capsule: relevance in clinical practice. *Therap Adv Gastroenterol*. 2012;5(4):249 to 260. doi:10.1177/1756283X12437874