

Clinical Policy: Wireless Motility Capsule

Reference Number: LA.CP.MP.143

Coding Implications

Date of Last Review-Revision Date:
08/202010/22

Revision Log

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The wireless motility capsule (WMC) assesses gastroparesis or delayed gastric emptying. The WMC is an orally ingested, nondigestible, data-recording device that enables the simultaneous assessment of regional and whole gut transit.²⁻⁴

Policy/Criteria

It is the policy of Louisiana Healthcare Connections 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. 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. ~~Additionally, in addition the WMC, it~~ 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.^{1,56}

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.⁶ An example of a wireless GI motility monitoring system is the SmartPill GI monitoring system 2.0.¹

Advantages of the WMC include that it is wireless and painless and contains no radiation. 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.⁹⁷ Patients ideally should be able to tolerate not using proton pump inhibitors and histamine 2 blockers before testing.⁸

Agency for Healthcare Research and Quality

Based on current literature, the 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. However, evidence is insufficient to determine whether use of the WMC will improve outcomes of care. One goal would be to define the populations who would benefit most from motility testing, including WMC testing.⁷⁹

American College of Gastroenterology

Scintigraphic gastric emptying of solids is the standard for the evaluation of gastric emptying and the diagnosis of gastroparesis.¹ Alternative approaches for assessment of gastric emptying include WMC~~wireless capsule motility~~ testing and 13C-spirulina ~~13-C~~ breath testing using octanoate or spirulina incorporated into a solid meal; they require further validation before they can be considered as alternates to scintigraphy for diagnosis of gastroparesis.³ (Conditional (conditional recommendation, moderate-low level of evidence).⁹

BlueCross BlueShield Association Technology Evaluation Center

This society concluded that the WMC does not meet the TEC~~technology evaluation center~~TEC criteria, but that the limited body of evidence on the diagnostic characteristics of SmartPill does reveal correlations between SmartPill and other tests that indicate some capability to distinguish diseased from non-diseased persons.²¹⁰

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.⁴¹¹

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.¹²

Other studies have noted that the sensitivity and specificity of the WMC is comparable to radiopaque marker test and scintigraphic gastric emptying.¹³ WMC is well tolerated, has good compliance, and avoids the risk of radiation exposure, h~~-~~However, it is not clear that it provides added clinical value in most patients. ^{1,66, 8, 4014}

Coding Implications

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

HCPSC Codes	Description
N/A	

ICD-10-CM Diagnosis Codes Related to Procedure

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

Reviews, Revisions, and Approvals	Date	Approval Date
Converted corporate to local policy.	08/15/2020	
Annual review. Criteria section updated with wording for abbreviation. Background updated with no impact on criteria. References reviewed and updated. Specialist reviewed.	10/22	

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.~~
- ~~2. BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Wireless motility capsule in the diagnosis and evaluation of gastroparesis or slow transit constipation. TEC Assessment Program. Chicago, IL: BCBSA; October 2012;27(4).~~
- ~~3. Camilleri M, Parkman HP, Shafi MA, et al. American College of Gastroenterology. Clinical guideline: management of gastroparesis. *Am J Gastroenterol*. 2013; 108(1):18-37.~~
- ~~4. 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):1269-1282.~~
- ~~5.1. Hayes Health Technology Assessment-. Hayes. www.hayesinc.com. Wireless Capsule Systems for Diagnosis of Gastroparesis and Monitoring of Gastrointestinal Motility. Published SeptemberSept 21, 2017, Update Nov (annual review October 26, 2021)19 Accessed August 19, 2022.Feb 10, 2020.~~
- ~~6. Lembo AJ. Overview of Gastrointestinal Testing. In: UpToDate. Talley NJ (Ed) UpToDate, Waltham, MA Accessed Feb, 10, 2020.~~
- ~~7.2. 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.x2011.~~

- ~~8. 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.~~
- ~~9. Stein E, Burger Z, Hutless S, et al. Wireless Motility Capsule Versus Other Diagnostic Technologies for Evaluating Gastroparesis and Constipation: A Comparative Effectiveness Review. Agency for Healthcare Research and Quality (US); 2013 May. Available at: <http://www.ncbi.nlm.nih.gov/books/NBK143974/>.~~
- ~~10. 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):249-260.~~
3. 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 SpringRockville, MD: FDA. ~~July 29~~October 30, 2009. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/K092342.pdf. Accessed August 19, 2022.
4. Local coverage determination: Wireless Gastrointestinal Motility Monitoring System (L33455). Centers for Medicare and Medicaid Services Web site. <http://www.cms.hhs.gov/mcd/search.asp>. Published October 01, 2015 (revised September 09, 2021). Accessed August 16, 2022.
5. 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
6. Lembo AJ. Overview of Gastrointestinal Testing. UpToDate. www.uptodate.com Published January 12, 2021. Accessed August 16, 2022.
7. 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.
8. 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
9. 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.0000000000001874f
10. Wireless motility capsule in the diagnosis and evaluation of gastroparesis or slow-transit constipation. *Technol Eval Cent Assess Program Exec Summ*. 2012;27(4):1 to 3.
11. 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
- ~~11.~~
12. 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):391-400. doi: 10.1111/apt.14438.
13. 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. 2018 Dec 14. pii: S1542-3565(18)31381-8. doi: 10.1016/j.cgh.2018.11.063

14. [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](#)

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

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