

# Clinical Policy: Wireless Motility Capsule

Reference Number: CP.MP.143

Date of Last Revision: 10/21

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## 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.

## Policy/Criteria

It is the policy of health plans affiliated with Centene Corporation® that 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 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; in addition, 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.<sup>6</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>6</sup> An example of a wireless GI motility monitoring system is the SmartPill GI monitoring system 2.0.

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.<sup>9</sup> Patients ideally should be able to tolerate not using proton pump inhibitors and histamine 2 blockers before testing.<sup>8</sup>

## *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

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improve outcomes of care. One goal would be to define the populations who would benefit most from motility testing, including WMC testing.<sup>9</sup>

*American College of Gastroenterology*

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 wireless capsule motility testing and 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.<sup>3</sup> (Conditional recommendation, moderate level of evidence)

*BlueCross BlueShield Association Technology Evaluation Center*

This society concluded that the WMC does not meet the 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.<sup>2</sup>

*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>4</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>12</sup>

Other studies have noted that the sensitivity and specificity of the WMC is comparable to radiopaque marker test and scintographic gastric emptying. WMC is well tolerated, has good compliance, and avoids the risk of radiation exposure. However, it is not clear that it provides added clinical value in most patients.<sup>6, 8, 10</sup>

**Coding Implications**

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CPT® 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 Code	Description
K31.84	Gastroparesis
K59.01	Slow transit constipation
K59.04	Chronic idiopathic constipation

Reviews, Revisions, and Approvals	Revision Date	Approval Date
New payment policy developed.	04/17	04/17
References reviewed and updated.	02/18	03/18
References reviewed and updated.	03/19	03/19
Revised statement in background from the American College of Gastroenterology. References reviewed and updated. Specialist reviewed.	02/20	03/20
Added language to the American College of Gastroenterology statement in background. References reviewed and updated. Replaced “member” with “member/enrollee” in all instances.	12/20	01/21
Annual review. Changed “review date” in the header to “date of last revision” and “date” in the revision log header to “revision date.” References reviewed and updated.	10/21	10/21

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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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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**Note: For Medicare members/enrollees**, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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