

### **Clinical Policy: Wireless Motility Capsule**

Reference Number: PA.CP.MP.143

Last Review Date: 10/2020 Effective Date: 7/30/2021 Coding Implications
Revision Log

#### **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 PA Health & Wellness (PHW)<sup>®</sup> 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 which 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. Patients ideally should be able to tolerate not using proton pump inhibitors and histamine 2 blockers before testing.

#### 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.<sup>9</sup>

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#### 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)

#### American Journal of Gastroenterology

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>2</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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## CLINICAL POLICY Wireless Motility Capsule



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

HCPCS	Description
Codes	
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
References reviewed and updated.		03/18
Annual review, no changes.		
Revised statement in background from the American College of Gastroenterology. References reviewed and updated. Specialist reviewed.		12/2020
Added language to the American College of Gastroenterology statement in background. References reviewed and updated. Replaced "member" with "member/enrollee" in all instances.		9/7/2021

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