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Kaiser Foundation Health Plan of Washington

Clinical Review Criteria
Wireless Motility Capsule

- SmartPill for the Evaluation of Gastrointestinal Motility Disorders

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, "***Wireless Motility Capsule***" for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

Effective until August 1, 2025

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

Effective August 1, 2025

Clinical criteria is archived and moved to Medically Necessary Services criteria page.

> The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Gastrointestinal (GI) symptoms including abdominal pain, bloating, vomiting, diarrhea, and constipation, are common in the general population and may lead to patient distress, impairment in functioning, and loss of productivity. Many of these symptoms may be linked to motility disorders, which may affect any region of the GI tract and include gastroparesis, intestinal pseudo-obstruction, and slow transit constipation. Gastroparesis is a chronic disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. It is manifested by upper GI symptoms including nausea, vomiting, early satiety, and objective evidence of delayed gastric emptying. Patients with slow transit constipation commonly present with lower GI symptoms such as abdominal pain, infrequent hard stools, and evidence of delayed colonic transit on objective testing. Sometimes it is hard to differentiate between upper and lower GI involvement and some patients may experience overlapping symptoms due to the involvement of multiple regions of the GI tract. In addition, signs of gastroparesis and chronic constipation are often confused with symptoms from conditions such as irritable bowel syndrome (IBS)

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and functional dyspepsia. It is thus important to localize the transit abnormalities to a specific GI lesion to accurately diagnose the disorder and guide the appropriate management (Williams 2011, Arora 2015, Gronlund 2017).

Motility disorders are hard to diagnose and cannot be measured by routine imaging or endoscopic examinations. A clinical diagnosis is based on physiological tests most of which have some inconsistency in performance, making it hard to interpret the results, and may require using more than one test to make a diagnosis. Experts in the field indicate that currently, there are no gold standards or true motility measures to validate methods used for the assessment of gut motility, and that no current standardized tool can concurrently assess transit time and distinguish between motility abnormalities in the various parts of the GI tract (Stein 2013, Gronlund, 2017).

Commonly used methods for evaluating patients with suspected gastroparesis include gastric emptying scintigraphy, antroduodenal manometry, upper GI barium series, and gastric emptying breath testing utilizing a stable carbon isotope. Scintigraphy is often considered the reference standard for measuring gastric emptying time despite its limitations. It involves exposure to radiation, and lacks standardization between centers as regards meal composition, monitoring times, reported endpoints, and normal values. It also takes long time periods of imaging and may require multiple visits to the investigating facility (Kuo 2008, Stein 2013, Wang 2015, Saad 2016).

The main diagnostic methods used for the evaluation of possible slow-transit constipation include radiopaque marker (ROM) examination, small bowel and colonic scintigraphy, colonic and anorectal manometry, and lactulose breath testing. ROM is widely used, and may be considered a reference standard, but has its drawbacks including radiation exposure, inability to access regional gut transit, and the lack of standardized protocol for the test and its interpretation. In addition, some protocols require multiple visits, which may affect compliance (Rao 2009, Sarosiek 2010, Tran 2012, Stein 2013, Saad 2016)

A wireless motility/pH gastrointestinal monitoring system was developed in 2003, as a radiation-free noninvasive alternative to traditional nuclear and radiological measurements used for the evaluation of GI motility disorder. The system provides a method of measuring regional and whole gut transit time in a single standardized ambulatory test. It consists of a wireless motility capsule (WMC, SmartPill), a SmartPill Data Receiver, a Docking Station, and a system computer loaded with SmartPill Software. WMC is a data recording device 26.8mm in length and 11.7mm in diameter (about the size of a large vitamin pill). It consists of a rigid polyurethane shell containing a battery that lasts for a minimum of 120 hours, sensors for pH, temperature, and pressure; and a transmitter. WMC is a single use, orally ingestible, non-digestible capsule that provides real-time measurement of the temperature, pressure, and pH of its immediate surrounding. It can measure gastric emptying time (GET), small bowel transit time (SBTT), colonic transit time (CTT), and whole gut transit time (WGTT), but does not provide information on segmental colonic transit times, i.e. it is unable to show where the motility disturbance originates in the colon. It is to be noted that WMC measures the emptying of a non-digestible solid, unlike the gastric emptying scintigraphy and breath testing that measure gastric emptying of digestible solids. WMC may not correspond to physiological emptying of food; it does not empty with the meal but is generally cleared from the stomach by powerful inter-digestive antral contractions (phase III MMC [migrating motor complex] contractions) that occur after the meal has been emptied to clear the stomach of indigestible material. Thus, as some investigators indicate, the passage of WMC into the duodenum correlates only modestly with the gastric emptying of nutrients (Kuo 2011, Saad 2011, 2016, Tran 2012, Shin 2013, Gronlund 2017, Keller 2018).

A WMC study can be performed in a physician's office after the patient undergoes an overnight fast and discontinues medication that may potentially affect gastric pH and GI motility. The WMC is swallowed with 50ml water immediately following a standardized meal (egg sandwich [255 kcal, 2% fat, 1g fiber], or a nutritionally equivalent Smart Bar [260 kcal, 2% fat, 2g fiber]). Patient are given a data receiver and a diary for recording bowel movements, food intake, sleep, and GI symptoms. They can leave the clinical setting after the absence of any complications from ingesting the capsule is confirmed. The patients are not permitted to eat for 6 hours after which, they are instructed to consume the regular meals for the testing period of 3-5 days; to avoid vigorous exercise; refrain from alcohol, smoking, and the use of GI medications that could affect motility. The capsule travels through the gastrointestinal tract, collecting, recording, and transmitting data to the SmartPill Data Receiver worn on a patient's belt or around the neck. It is then excreted naturally from the body within a day or two. The data recorder is returned to the physician’s office and the information downloaded via a docking station for analysis (Rao 2009, Saad 2011).

The SmartPill GI Monitoring System (WMC SmartPill®, SmartPill Corporation, Buffalo, NY, USA; now Medtronic, Minneapolis, MN, USA), was cleared by the Food and Drug Administration (FDA) in July 2006, for the evaluation

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of delayed gastric emptying in the absence of mechanical obstruction. 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 or versus normal transit constipation.

The WMC testing is not approved for use in the pediatric population and is not indicated for the diagnosis of IBS or functional dyspepsia. It is contraindicated in patients with suspected or known swallowing disorders; strictures, fistulas, or physiological/mechanical GI obstruction; GI surgery within the past 3 months; severe dysphagia to food or pills; Crohn's disease or diverticulitis; implanted or portable electro-mechanical medical device; or a history of gastric bezoar (a ball of swallowed foreign material most often composed of hair or fiber). WMC is also contraindicated in patients with a cardiac pacemaker or defibrillator due to concerns related to the capsule's radio transmission of data to the receiver (Farmer 2013, Saad 2016).

Reported adverse events and /or equipment failure associated with WMC testing, include inability of the patient to swallow the capsule, equipment failure of the capsule to record or transmit data, failure of the receiver to record and download data, and software malfunction necessitating repeat testing. The most severe, but rare adverse event reported was the capsule retention in the stomach, small intestine or colon, which required operative removal of the device in a small number of patients. Other reported side effects include abdominal pain, dysphagia, nausea, and diarrhea (Saad 2016).

Medical Technology Assessment Committee (MTAC)

Wireless Motility Capsule (WMC; SmartPill) for the Evaluation of Gastrointestinal Motility Disorders

01/14/2019: MTAC REVIEW

Evidence Conclusion:

Diagnostic accuracy of wireless motility capsule (WMC)

- It is difficult to estimate the accuracy of a test when there is no standardized gold standard to compare it with. The reference standards commonly used in practice and in the literature, are mainly gastric scintigraphy for gastroparesis and radiopaque markers (ROM) for colonic transit disorders. These may be considered reference tests, but according to the experts on the field, none is a perfect test. In addition, the tests are not usually conducted according to a standardized technique protocol as regards meal composition, monitoring times, and interpretation. Moreover, WMC and the reference tests were not always performed simultaneously (in some cases conventional tests were performed months earlier) which would not provide accurate comparison as patients with dysmotility may have major day-to-day variability on repeat transit testing. The upper limits for small and large bowel transit times measured by WMC differed between some studies. WMC measures the emptying of a non-digestible solid, unlike the gastric emptying scintigraphy and breath testing that measure gastric emptying of digestible solids. WMC does not empty with the meal but is generally cleared from the stomach powerful inter-digestive antral contractions that occur after the meal has been emptied to clear the stomach of indigestible material.
- The published literature shows wide variations in the calculated accuracy of the wireless motility capsule for the diagnosis of GI dysmotility. The sensitivity of WMC ranged from 59% to 86%, and its specificity ranged from 64% to 81% for gastroparesis when compared with gastric scintigraphy; the overall concordance between the tests ranged from 35% to 81%.
- When compared with radiopaque markers (ROM) for the detection of slow-transit constipation, WMC had a sensitivity of 43-87% and specificity of 67-98%. The concordance ranged between 64% and 87%.
- WMC was found to be less accurate than barium testing of small bowel dysmotility disorders.
- The analysis of the results from one study (Wang, 2015) suggests that regional GI transit time and pH values measured by the WMC may be affected by the testing protocol, gender, age, and country where the test is performed. The authors thus concluded that standardization of the test is essential for cross referencing in clinical practice and research; and presented normative values for regional transit times for reference in clinical practice.
- The results were based on the analyses of prospectively or retrospectively collected data from records of patients referred to tertiary centers specializing in managing severe dysmotility disorders. Retrospective studies have their limitations and are subject to bias and confounding. Patients referred for further investigations in tertiary centers tend to have more severe symptoms, are refractory to therapy and/or have failed several conventional tests. This would affect the accuracy and predictive value of the test and limit generalization of the results.

Safety of WMC

The published studies do not provide sufficient data to determine the safety of WMC.

Clinical utility of WMC

- The literature search did not identify any randomized controlled trials the examined the clinical utility of using WMC in patients with GI motility disorders, i.e. it impacts on managing the patients and improving their health outcomes. All

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published studies were secondary analyses of prospectively or retrospectively collected patient data obtained from chart reviews or electronic health records.

- The published secondary analyses of data provide weak evidence suggesting WMC may provide more diagnostic information compared to conventional methods used for evaluating gastrointestinal motility disorders, and the modification of the management plans.
- There is insufficient evidence to determine that the use of WMC improves the health outcomes of patients with gastrointestinal motility disorders.

Articles: The literature search identified an earlier comprehensive AHRQ systematic review (Stein et al, 2013) on the comparative effectiveness of wireless motility capsule and other diagnostic technologies used for evaluating gastroparesis and constipation. The search for studies published after the AHRQ literature review identified over 50 publications; the majority of which were review articles or studies unrelated to the current review. Related articles included two recent observational studies on the diagnostic performance of WMC in patients with suspected gastroparesis, a study that examined the influence of several variables on the outcomes of the WMC testing, two studies on the use of WMC in the assessment of GI dysmotility in patients with diabetes mellitus, and few retrospective studies on the clinical utility of WMC in patients with GI dysmotility. The results of the AHRQ systematic review on the comparative accuracy of WMC vs. alternative tests used for the diagnosis GI dysmotility, as well as the recent validation studies, the study on the variables affecting the outcome of the test, and selected studies evaluating the clinical utility of WMC and using gastric scintigraphy and ROM as reference standards for evaluating the accuracy of WMC for upper and lower GI dysmotility respectively were reviewed and summarized.

The use of Wireless Motility Capsule (WMC; SmartPill) for the Evaluation of Gastrointestinal Motility Disorders does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

Applicable Codes

Considered Not Medically Necessary

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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
02/05/2019	02/05/2019[MPC], 01/07/2020[MPC], 01/05/2021[MPC], 01/04/2022[MPC], 01/10/2023[MPC], 03/12/2024[MPC], 03/04/2025[MPC]	03/04/2025

[MPC] Medical Policy Committee

Revision History	Description
02/05/2019	MPC approved to adopt criteria of non-coverage; added 01/2019 MTAC review
03/04/2025	MPC approved to archive the policy and move to the Medically Necessary Services policy. Requires 60-day notice, effective August 1st, 2025.

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