FEP 2.01.81 Ingestible pH and Pressure Capsule

Effective Date: April 15, 2018

Related Policies:
2.01.20 Esophageal pH Monitoring
6.01.33 Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus and Colon

Ingestible pH and Pressure Capsule

Description

An ingestible pH and pressure-sensing capsule (SmartPill GI Monitoring System) measures pH, pressure, and temperature changes to signify the passage of the capsule through portions of the gastrointestinal tract. It is proposed as a means of evaluating gastric emptying for diagnosis of gastroparesis, and colonic transit times for the diagnosis of slow-transit constipation.

FDA REGULATORY STATUS

In 2006, an ingestible capsule (SmartPill® GI Monitoring System; Given Imaging) was cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, for evaluation of delayed gastric emptying. Gastric emptying is signaled when the pH monitor in the capsule indicates a change in pH from the acidic environment of the stomach to the alkaline environment of the small intestine. For example, an increase of 2 or more pH units usually indicates gastric emptying, and a subsequent decrease of 1 or more pH units usually indicates a passage to the ileocecal junction. While SmartPill® does not measure 50% emptying time, it can be correlated with scintigraphically measured 50% emptying time. The capsule also measures pressure and temperature during its transit through the entire gastrointestinal tract, allowing calculations of total gastrointestinal tract transit time. In 2009, the Food and Drug Administration expanded the use of the SmartPill® to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow- and normal- transit constipation. When colonic transit time cannot be determined, small and large bowel transit times combined can be used instead. The SmartPill® is not for use in pediatric patients.

POLICY STATEMENT

Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered **investigational** for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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RATIONALE

Summary of Evidence

For individuals who have suspected disorders of gastric emptying or suspected slow-transit constipation who receive diagnostic testing with an ingestible pH and pressure capsule, the evidence includes studies of test characteristics and case series of patients who have undergone the test. Relevant outcomes are test accuracy and validity, other performance measures, symptoms, functional outcomes, and health status measures. The available studies have provided some comparative data on the SmartPill ingestible pH plus pressure-sensing capsule and other techniques for measuring gastric emptying and colonic transit times. This evidence primarily consists of assessments of concordance with available tests. Because the available tests (eg, gastric emptying scintigraphy) are imperfect criterion standards, it is not possible to determine the true sensitivity and specificity of SmartPill. The results of the concordance studies have revealed a moderate correlation with alternative tests, but have provided only limited additional data on the true accuracy of the test in clinical care. Evaluation of cases with discordant results would be of particular value and, ideally, these studies should be linked to therapeutic decisions and to meaningful clinical outcomes. The evidence to date on the clinical utility of testing is lacking, consisting of a small number of retrospective studies. It is not possible to determine whether there is net improvement in health outcomes using SmartPill vs standard diagnostic tests. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Neurogastroenterology and Motility Society

The American Neurogastroenterology and Motility Society issued a consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice in 2008.[14] In this consensus statement, formal recommendations on any type of test were not issued. It was noted that SmartPill could be used to identify delayed gastric emptying, but that the impact of the technology on patient management has not been studied. Use of SmartPill to assess colonic motility was noted, but no mention was made of its use to measure colonic transit time.

American and European Neurogastroenterology and Motility Societies

The American and European Neurogastroenterology and Motility Societies issued a position paper on the evaluation gastrointestinal transit in 2011.[15] In it, the wireless motility capsule was recommended by consensus for assessing gastric emptying and small bowel, colonic, and whole-gut transit times in patients with suspected gastroparesis or gastrointestinal dysmotility in multiple regions. However, the position paper noted that the clinical utility of identifying delays in small bowel transit times is unknown.

American Gastroenterological Association

The American Gastroenterological Association's 2013 guidelines on gastroparesis diagnosis and treatment indicated wireless motility capsule testing requires validation before it can be considered as an alternative to scintigraphy for diagnosing gastroparesis.[16] Gastric emptying scintigraphy was considered the best-accepted method to test for delays in gastric emptying.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

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POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
June 2012	Replace Policy	Policy statement amended to include measurement of whole gut transit time and evaluation of gut motility disorders other than gastroparesis and not medically necessary. References 10, 11, 12, 14 and 15 added.
June 2013	Update Policy	Policy updated with literature review. References added. Policy statement unchanged.
June 2014	Update Policy	Policy updated with literature review, references 4 and 14 added. Policy statement unchanged.
June 2015	Update Policy	Policy updated with literature review. Reference 15 added. Policy

		statement unchanged.
June 2016	Update Policy	Policy updated with literature review through October 15, 2015; references 8 and 13 added. Policy statement unchanged
March 2016	Update Policy	Policy updated with literature review; no references added. Policy statement unchanged.
March 2018	Update Policy	Policy updated with literature review through September 14, 2017; no references added. Policy statement unchanged except not medically necessary corrected to investigational due to 510k FDA status.