FEP Medical Policy Manual

FEP 2.01.81 Ingestible pH and Pressure Capsule

Effective Policy Date: April 2020

Original Policy Date: December 2011

Related Policies:

6.01.33 - Wireless Capsule Endoscopy to Diagnose 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.

OBJECTIVE

The objective of this evidence review is to determine whether diagnostic testing with an ingestible pH and pressure capsule improves the net health outcome in persons being evaluated for gastroparesis, constipation, or other gastrointestinal motility disorders.

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.

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

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.

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 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. 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 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.[8] 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.[9] 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. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Abell TL, Camilleri M, Donohoe K, et al. Consensus recommendations for gastric emptying scintigraphy: a joint report of the American Neurogastroenterology and Motility Society and the Society of Nuclear Medicine. J Nucl Med Technol. Mar 2008;36(1):44-54. PMID 18287197.

2. Parkman HP, Hasler WL, Fisher RS. American Gastroenterological Association technical review on the diagnosis and treatment of gastroparesis. Gastroenterology. Nov 2004;127(5):1592-1622. PMID 15521026.

3. Tougas G, Eaker EY, Abell TL, et al. Assessment of gastric emptying using a low fat meal: establishment of international control values. Am J Gastroenterol. Jun 2000;95(6):1456-1462. PMID 10894578.

4. Stein E, Berger Z, Hutfless 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; 2013.

5. Green AD, Belkind-Gerson J, Surjanhata BC, et al. Wireless motility capsule test in children with upper gastrointestinal symptoms. J Pediatr. Jun 2013;162(6):1181-1187. PMID 23290514.

6. Kuo B, Maneerattanaporn M, Lee AA, et al. Generalized transit delay on wireless motility capsule testing in patients with clinical suspicion of gastroparesis, small intestinal dysmotility, or slow transit constipation. Dig Dis Sci. Oct 2011;56(10):2928-2938. PMID 21625964.

7. Rao SS, Mysore K, Attaluri A, et al. Diagnostic utility of wireless motility capsule in gastrointestinal dysmotility. J Clin Gastroenterol. Sep 2011;45(8):684-690. PMID 21135705.

8. 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. Jan 2011;23(1):8-23. PMID 21138500.

9. Camilleri M, Parkman HP, Shafi MA, et al. Clinical guideline: management of gastroparesis. Am J Gastroenterol. Jan 2013;108(1):18-37; quiz 38. PMID 23147521.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
Decmeber 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	Replace policy	Policy updated with literature review. References added. Policy statement unchanged.
June 2014	Replace policy	Policy updated with literature review, references 4 and 14 added. Policy statement unchanged.
June 2015	Replace policy	Policy updated with literature review. Reference 15 added. Policy statement unchanged.
June 2016	Replace policy	Policy updated with literature review through October 15, 2015; references 8 and 13 added. Policy statement unchanged.
March 2017	Replace policy	Policy updated with literature review; no references added. Policy statement unchanged.
March 2018	Replace 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.
March 2019	Replace policy	Policy updated with literature review through September 4, 2018; no references added. Policy statement unchanged.
March 2020	Replace policy	Policy updated with literature review through September 23, 2019; no references added. Policy statement unchanged.