



Louisiana

Ingestible pH and Pressure Capsule

Policy # 00470

Original Effective Date: 06/17/2015

Current Effective Date: 06/20/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Wireless Capsule Endoscopy as a Diagnostic Technique in Disorders of the Small Bowel, Esophagus, and Colon is addressed separately in medical policy 00137.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders to be **investigational**.*

Background/Overview

GASTROPARESIS AND CONSTIPATION

Gastroparesis is a chronic disorder characterized by delayed gastric emptying in the absence of mechanical obstruction. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal tract disorders. It can be caused by many conditions; most commonly it is idiopathic, diabetic, or postsurgical.

Constipation is a chronic disorder involving infrequent bowel movements, a sensation of obstruction, and incomplete evacuation. Many medical conditions can cause constipation, such as mechanical obstruction, metabolic conditions, myopathies, and neuropathies. Diagnostic testing for constipation can aid in distinguishing between 2 categories of disorders, slow-transit constipation and pelvic floor dysfunction.

Diagnosis

Gastric emptying scintigraphy is considered the reference standard for diagnosing gastroparesis. The patient ingests a radionuclide-labeled standard meal and subsequent imaging is performed at 0, 1, 2, and 4 hours postprandially, to measure how much of the meal has passed beyond the stomach. A typical threshold to indicate abnormal gastric emptying is more than 10% of the meal remaining at 4 hours after ingestion.

Standard tests used in the evaluation of constipation include ingestion of radiopaque markers and colonic transit scintigraphy. In the radiopaque markers test, small markers are ingested over 1 or several days, and abdominal radiographs are performed at 4 and/or 7 days. The number of remaining markers correlates with the colonic transit time. In colonic transit scintigraphy, a radio-labeled meal is ingested, followed by

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scintigraphic imaging at several time intervals. The location of the scintigraphic signals correlates with colonic transit times.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2006, an ingestible capsule (SmartPill[®] GI Monitoring System; Given Imaging) was cleared for marketing by the U.S. FDA 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 FDA 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.

Centers for Medicare and Medicaid Services (CMS)

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

Rationale/Source

Assessment of diagnostic technology typically focuses on 3 categories of evidence: (1) technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, positive and negative predictive values) in relevant populations of patients; and (3) clinical utility (ie, demonstration that the diagnostic information can be used to improve patient outcomes). Additionally, when considering invasive monitoring, any improvements in patient outcomes must be outweighed by device-related risks associated with testing. The following is a summary of the key literature to date.

WIRELESS PH AND PRESSURE CAPSULES

Technical Reliability

We did not identify any literature assessing the technical reliability of wireless pH pressure capsules.

Clinical Validity

Gastric Emptying

Although scintigraphy is considered the reference standard for evaluating gastric emptying, several issues complicate its use as a reference test. Until recently, there has been a lack of test standardization. Significant day-to-day variability in the rate of gastric emptying has also been noted.

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Due to a lack of standardization and small sample sizes referenced in published studies, the capability of the gastric emptying test to discriminate between healthy individuals and those with known gastroparesis is uncertain. In a 2000 study by Tougas et al, 123 healthy subjects were assessed to determine the normal period required for nearly complete evacuation of a standardized meal from the stomach. The authors suggested that the threshold of normality for gastric retention at 4 hours is 10% meal retention. The cutoff point was set to include 95% of normal persons. However, it appears to be unknown if this same threshold adequately identifies persons who would otherwise be classified as having gastroparesis and who are candidates or responders to treatment.

A few published studies have evaluated the ingestible capsule in relation to another diagnostic measure of gastric emptying. A 2013 systematic review of 12 studies on the ingestible capsule was published by the Agency for Healthcare Research and Quality (AHRQ). Studies that included only healthy participants were excluded from the review; instead, AHRQ looked for studies with comparison groups consisting of healthy, asymptomatic (ie, without symptoms of gastroparesis or constipation) participants as controls, thus limiting interpretation of the comparisons. Among these studies, the overall strength of evidence favoring the ingestible capsule was low. Diagnostic accuracy with the ingestible capsule was considered comparable to gastric scintigraphy in 7 studies, with diagnostic agreement ranging from 58% to 86% for test agreement when results were positive and 64% to 81% when results were negative. There was a moderate correlation between the ingestible capsule and gastric emptying scintigraphy on transit data and device agreement in 5 studies. Three studies that evaluated transit time reported similar sensitivity and specificity rates for the ingestible capsule and scintigraphy.

In 2008, Cassilly et al evaluated the SmartPill and simultaneous gastric emptying scintigraphy in 15 healthy subjects. The capsule was ingested immediately following the radiolabeled test meal. In this study, the mean time for 50% gastric emptying by scintigraphy was 95 minutes, 90% gastric emptying by scintigraphy was 194 minutes, and gastric residence time by SmartPill was 261 minutes. The correlation coefficient (r) between SmartPill and 50% gastric emptying time was 0.606, and between SmartPill and 90% gastric emptying time it was 0.565. The average amount of meal remaining in the stomach at the time the SmartPill exited the stomach was 5.4%. This study showed an only modest correlation between the SmartPill and gastric emptying scintigraphy and was too small to establish reference values for the SmartPill.

In a 2008 study by Kuo et al, 87 healthy subjects and 61 subjects with symptoms and prior positive test results for gastroparesis were evaluated with both the SmartPill and gastric emptying scintigraphy. In this study, subjects ingested the capsule just before consuming the standard meal. This led to the premature passage of the SmartPill in 5 subjects (<30 minutes) whose tests were subsequently considered invalid. Sixteen other subjects had equipment malfunctions, and two others dropped out.

Among the remaining 125 subjects, the correlation coefficient (r) between SmartPill gastric emptying time and scintigraphy at 2 hours was 0.63, and between SmartPill gastric emptying time and scintigraphy at 4 hours was 0.73. Regarding the capability to discriminate between gastroparetic patients and healthy subjects, the area under the curve was 0.83 for SmartPill, 0.82 for scintigraphy at 4 hours, and 0.79 for

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scintigraphy at 2 hours (all $p > 0.05$), indicating the similar capability of each for discriminating between the 2 patient groups. At a cutoff point of 300 minutes for the SmartPill, which was established by calculating the ideal cutoff point from the data, the sensitivity was 65%, and specificity was 87%. The sensitivity and specificity for scintigraphy, using an established cutoff point from the literature of 10% at 4 hours, was 44% and 93%, respectively.

Regarding adverse events reported by Kuo et al, 5 (7%) of 67 subjects who did not retrieve the capsule required a second additional plain radiograph beyond 5 days to demonstrate that the capsule had been passed. Another patient ingested a laxative that caused the capsule to be entrapped in a viscous mass. An unsuccessful endoscopy ensued, followed by treatment with intravenous erythromycin to pass the capsule from the stomach.

A 2009 study by Maqbool et al assessed SmartPill and gastric emptying scintigraphy in 10 healthy asymptomatic subjects. Emptying time assessed by SmartPill correlated with the percent meal retained at 2 and 4 hours. The correlation coefficient (r) between SmartPill and 2-hour scintigraphy was 0.95. The correlation between SmartPill and 4-hour scintigraphy was 0.73.

A 2013 study by Green et al assessed SmartPill and gastric emptying scintigraphy in 22 pediatric patients with severe upper gastrointestinal (GI) symptoms. Of 20 evaluable patients who had both tests, 9 patients had delayed gastric emptying identified by scintigraphy. SmartPill was 100% sensitive and 50% specific for delayed gastric emptying. Patients also underwent antroduodenal manometry to detect motor abnormalities. SmartPill identified motor abnormalities in 17 patients compared with 10 detected by antroduodenal manometry. However, there does not appear to be a reference standard for motor abnormalities. Thus it cannot be determined whether SmartPill is more sensitive or whether it has a higher false-positive rate for detection of motor abnormalities.

Section Summary: Clinical Validity for Gastric Emptying

The data present several shortcomings on the use of the SmartPill in diagnosing gastroparesis; as a result, the diagnostic accuracy is not well defined. The current reference test (gastric emptying scintigraphy) is an imperfect criterion standard, and this creates difficulties in defining the sensitivity and specificity of SmartPill. All studies cited here included healthy asymptomatic subjects either entirely or as part of a control group. Healthy subjects are not a fair representation of the clinically relevant group under consideration for a diagnosis of delayed gastric emptying. Ideally, the relevant population of subjects should be symptomatic or under evaluation for a diagnosis of gastroparesis. Although there was a moderate correlation between SmartPill gastric emptying time and scintigraphy, scintigraphy itself has limited reliability. Although the areas under the curve between SmartPill and scintigraphy are similar, the modest correlation between the 2 tests indicates that there are often discordant results.

Colonic Transit Time

Few studies have evaluated the use of SmartPill for assessing colonic transit times. In the 2013 systematic review by AHRQ, the strength of evidence in available studies on the ingestible capsule was found to be

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low overall. Accuracy of the ingestible capsule in diagnosing slow-transit constipation was similar to tests using radiopaque markers and scintigraphy. The moderate correlation between colonic transit times with the ingestible capsule and tests with radiopaque markers was shown in 5 studies (r range, 0.69-0.71).

In the 2009 study by Maqbool et al (discussed earlier), healthy asymptomatic subjects underwent simultaneous whole-gut scintigraphy and SmartPill assessment of whole-gut transit times. The 2 techniques correlated with each other reasonably well. In a 2009 study by Rao et al, healthy subjects and subjects with constipation had whole-gut transit times assessed with radiopaque markers and the SmartPill. Diagnostic accuracy of the 2 techniques in differentiating between the 2 groups of patients were similar. Camilleri et al (2010) compared the wireless motility capsule with radiopaque markers in 158 patients with chronic functional constipation. In this multicenter validation study, the authors reported that positive percent agreement between the wireless motility capsule and radiopaque markers was approximately 80% for colonic transit time (95% confidence interval, 67% to 98%). No serious adverse events were reported.

The U.S. FDA has received 1 adverse event report (according to their MAUDE [Manufacturer and User Facility Device Experience] database), in which the capsule was trapped in the stomach of a patient and required endoscopic removal.

Section Summary: Clinical Validity for Colonic Transit Time

Although the studies cited here showed moderate correlations between SmartPill and other methods for assessing colonic transit times, they should be interpreted cautiously. Two studies included healthy subjects, who are not the appropriate comparator sample needed to evaluate a diagnostic test. These studies also did not identify a population with known slow-transit constipation, which is the clinically relevant subset of patients with constipation that the test seeks to identify. Thus, the diagnostic capability of SmartPill for detecting slow-transit constipation is unknown.

Clinical Utility

Gastric Emptying and Colonic Transit Times

The clinical utility of the test depends on the frequency, duration, and interpretation of imaging and is affected by factors including the use of different test meals and patient positioning. Demonstration of clinical utility further requires that technology is associated with change(s) in management that lead to improved health outcomes.

The 2013 AHRQ review found that there was a lack of evidence on the clinical utility of testing with the ingestible capsule. Therefore, the evidence was insufficient to conclude the impact of testing results of the ingestible capsule on treatment and management decisions.

In a 2011 retrospective study by Kuo et al, 83 patients were evaluated for gastroparesis, small intestinal dysmotility, and slow-transit constipation; the authors found that wireless motility capsule testing resulted in a new diagnosis in 44 (53%) patients. Changes to clinical management were recommended for 65 patients and included adjustments in medication regimens in 39 (60%) patients and in nutrition programs in 9 (14%)

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patients. Four (6%) patients were referred to surgery for colectomy. Abnormal gastric emptying or small intestinal transit times each did not influence patient management ($p=NS$). Abnormal colonic transit times did not influence nutritional program changes ($p=0.72$) but did influence medication changes ($p=0.02$) and resulted in a trend toward increased surgical referrals ($p=0.12$). The authors suggested that wireless motility capsule testing eliminated the need for nuclear gastric emptying testing in 9 (17%) of 52 patients, barium radiography testing in 7 (54%) of 13 patients, and radiopaque marker testing in 41 (68%) of 60 patients. They also noted a need for prospective studies to further understand wireless motility capsule testing and its role in patient management.

In a 2011 retrospective study of 86 patients with persistent symptoms of GI dysmotility despite normal endoscopic and radiologic test results, Rao et al found that evaluations using wireless motility capsule testing resulted in new diagnostic information in 26 (53%) of 50 patients with lower GI symptoms and in 17 (47%) of 36 patients with upper GI symptoms. Clinical management was influenced by wireless motility capsule testing in 30% of patients with lower gastrointestinal symptoms and in 50% of patients with upper GI symptoms. The retrospective nature of this study limits interpretation of results.

In a 2015 retrospective review of patients who underwent evaluation with SmartPill for suspected multiregional GI dysmotility, Arora et al reported abnormal test results in 109 (67.7%) of 161 of subjects. Of these patients, multiregional dysmotility was diagnosed in 54 (49.5%). Although this study demonstrated a high diagnostic yield among patients with a particular suspected condition, it did not demonstrate improved patient outcomes compared with standard tests.

Section Summary: Clinical Utility

Evidence on the clinical utility of a wireless pressure capsule is very limited, consisting of 3 retrospective analyses describing outcomes of patients undergoing testing with SmartPill. These studies lacked control subjects diagnosed without the test or with alternative tests. This evidence is insufficient to determine the clinical utility of SmartPill for either indication; higher quality studies are still needed to measure the impact of SmartPill on patient management and improved health outcomes.

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

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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.

References

1. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Ingestible pH and Pressure Capsule", 2.01.81, 11:2017.
2. 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
3. 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
4. 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
5. 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.
6. Cassilly D, Kantor S, Knight LC, et al. Gastric emptying of a non-digestible solid: assessment with simultaneous SmartPill pH and pressure capsule, antroduodenal manometry, gastric emptying scintigraphy. *Neurogastroenterol Motil*. Apr 2008;20(4):311-319. PMID 18194154
7. Kuo B, McCallum RW, Koch KL, et al. Comparison of gastric emptying of a nondigestible capsule to a radio-labelled meal in healthy and gastroparetic subjects. *Aliment Pharmacol Ther*. Jan 15 2008;27(2):186-196. PMID 17973643
8. Maqbool S, Parkman HP, Friedenbergl FK. Wireless capsule motility: comparison of the SmartPill GI monitoring system with scintigraphy for measuring whole gut transit. *Dig Dis Sci*. Oct 2009;54(10):2167-2174. PMID 19655250
9. 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
10. Rao SS, Kuo B, McCallum RW, et al. Investigation of colonic and whole-gut transit with wireless motility capsule and radiopaque markers in constipation. *Clin Gastroenterol Hepatol*. May 2009;7(5):537-544. PMID 19418602
11. Camilleri M, Thorne NK, Ringel Y, et al. Wireless pH-motility capsule for colonic transit: prospective comparison with radiopaque markers in chronic constipation. *Neurogastroenterol Motil*. Aug 2010;22(8):874-882, e233. PMID 20465593
12. 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
13. 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
14. Arora Z, Parungao JM, Lopez R, et al. Clinical utility of wireless motility capsule in patients with suspected multiregional gastrointestinal dysmotility. *Dig Dis Sci*. May 2015;60(5):1350-1357. PMID 25399332
15. Camilleri M, Bharucha AE, di Lorenzo C, et al. American Neurogastroenterology and Motility Society consensus statement on intraluminal measurement of gastrointestinal and colonic motility in clinical practice. *Neurogastroenterol Motil*. Dec 2008;20(12):1269-1282. PMID 19019032
16. 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
17. 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

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Original Effective Date: 06/17/2015

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06/04/2015 Medical Policy Committee review

06/17/2015 Medical Policy Implementation Committee approval. New policy.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

06/02/2016 Medical Policy Committee review

06/20/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

06/01/2017 Medical Policy Committee review

06/21/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

06/07/2018 Medical Policy Committee review

06/20/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2019

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	91112
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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