

BSC2.17 Ingestible pH and Pressure Capsule			
Original Policy Date:	April 2, 2010	Effective Date:	April 1, 2025
Section:	2.0 Medicine	Page:	Page 1 of 9

## Policy Statement

- I. 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.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

### Coding

See the [Codes table](#) for details.

## 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.

## Related Policies

- Esophageal pH Monitoring
- Wireless Capsule Endoscopy for Gastrointestinal (GI) Disorders

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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 (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.

## Rationale

### Background

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

### Literature Review

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

### Wireless pH and Pressure Capsules

#### Clinical Context and Test Purpose

The purpose of diagnostic testing with an ingestible pH and pressure capsule in patients who have suspected disorders of gastric emptying or have suspected slow-transit constipation is to inform a decision whether to proceed to appropriate treatment.

The question addressed in this evidence review is: Does diagnostic testing with an ingestible pH and pressure capsule improve the net health outcome in individuals with suspected disorders of gastric emptying or with suspected slow-transit constipation?

The following PICO was used to select literature to inform this review.

### ***Populations***

The relevant population of interest is individuals with suspected disorders of gastric emptying or with suspected slow-transit constipation.

### ***Interventions***

The test being considered is diagnostic testing with an ingestible pH and pressure capsule.

### ***Comparators***

The following tests are currently being used to diagnose suspected disorders of gastric emptying or slow-transit constipation: scintigraphy and radiopaque markers.

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.<sup>1</sup> Significant day-to-day variability in the rate of gastric emptying has also been noted.<sup>2</sup>

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 study by Tougas et al (2000), 123 healthy subjects were assessed to determine the normal period required for nearly complete evacuation of a standardized meal from the stomach.<sup>3</sup> 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.

### ***Outcomes***

The general outcomes of interest are reductions in gastrointestinal discomfort and pain and improvements in quality of life. Comparisons between the ingestible capsule and scintigraphy could be done concurrently.

### **Technically Reliable**

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

### **Clinically Valid**

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

### **Gastric Emptying**

#### **Systematic Reviews**

A few published studies have evaluated the ingestible capsule in relation to another diagnostic measure of gastric emptying. A systematic review of 12 studies on the ingestible capsule was conducted by Stein et al (2013) for the Agency for Healthcare Research and Quality (AHRQ; see Table 1).<sup>4</sup> Studies that included only healthy participants were excluded from the review; instead, AHRQ looked for studies with comparison groups consisting of healthy, asymptomatic (i.e., without

symptoms of gastroparesis or constipation) participants as controls. Among these studies, 5 were only available as meeting presentations, and 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, 3 of which were in abstracts only. There was a moderate correlation between the ingestible capsule and gastric emptying scintigraphy on transit data and device agreement in 5 studies.

**Table 1. Characteristics and Results of Systematic Reviews**

Study	Studies Included	Study Populations Included	Study Designs Included	Study Reference Standards Included	Sens, %	Spec, %	SOE
Stein et al (2013) <sup>4</sup> (AHRQ)	12	Patients with gastroparesis or constipation or healthy controls	7 studies were prospective, 5 of 7 were multicenter	Scintigraphy	59-86	64-81	Low

AHRQ: Agency for Healthcare Research and Quality; Sens: sensitivity; SOE: strength of evidence; Spec: specificity.

### Diagnostic Studies

A study by Green et al (2013) assessed SmartPill and gastric emptying scintigraphy in 22 pediatric patients with severe upper gastrointestinal (GI) symptoms.<sup>5</sup> 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, because there does not appear to be a reference standard for motor abnormalities, 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. Studies included healthy asymptomatic subjects as part of a control group. 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.

### Constipation

Few studies have evaluated the use of SmartPill for assessing colonic transit times. In the systematic review by Stein et al (2013) conducted for AHRQ, the strength of evidence in available studies on the ingestible capsule was found to be low overall.<sup>4</sup> No studies were identified that compared the SmartPill to colonic scintigraphy. Accuracy of the ingestible capsule in diagnosing slow-transit constipation was similar to tests using radiopaque markers. A 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).

### Section Summary: Clinical Validity for Constipation

Although the studies included in the AHRQ systematic review showed moderate correlations between SmartPill and other methods for assessing colonic transit times, they should be interpreted cautiously. The diagnostic capability of SmartPill for detecting slow-transit constipation is unknown.

### Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

### Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials. No randomized controlled trials were identified.

### Gastric Emptying and Constipation

The 2013 AHRQ review found that there was a lack of evidence on the clinical utility of testing with the ingestible capsule.<sup>4</sup> The review found 3 studies, including 1 abstract, on management changes following use of the SmartPill. Kuo et al (2011)<sup>6</sup> and Rao et al (2011)<sup>7</sup> reported that wireless motility capsule testing resulted in a new diagnosis in about 50% of patients. Due to the limited data, AHRQ reviewers considered the evidence insufficient to determine the impact of testing results of the ingestible capsule on treatment and management decisions.

### Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of an ingestible pH and pressure capsule has not been established, a chain of evidence supporting the clinical utility of the device cannot be constructed.

### Section Summary: Clinically Useful

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 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 (e.g., 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

In 2011, the American and European Neurogastroenterology and Motility Societies issued a position paper on the evaluation gastrointestinal transit.<sup>8</sup> 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

In 2013, the American Gastroenterological Association's 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.<sup>9</sup> 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.

### Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in August 2020 did not identify any ongoing or unpublished trials that would likely influence this review.

## 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): 1592-622. 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): 1456-62. 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): 1181-7. 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): 2928-38. 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): 684-90. 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

### Documentation for Clinical Review

- No records required

### Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	91112	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
HCPCS	None	

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
04/02/2010	New Policy Adoption
01/21/2011	Coding Update
02/22/2013	Coding Update
03/29/2013	Policy revision with position change
06/30/2015	Policy revision without position change
04/01/2016	Policy revision without position change
12/01/2016	Policy revision without position change
10/01/2017	Policy revision without position change
01/01/2018	Policy revision without position change
01/01/2019	Policy revision without position change
01/01/2020	Annual review. No change to policy statement. Literature review updated.
01/01/2021	Annual review. No change to policy statement. Literature review updated.
03/01/2022	Annual update. Adopted as custom policy. No change to policy statement.
03/01/2023	Annual review. No change to policy statement.
03/01/2024	Annual review. No change to policy statement.
04/01/2025	Annual review. No change to policy statement.



## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*



Appendix A

POLICY STATEMENT (No changes)	
BEFORE	AFTER
<p>Ingestible pH and Pressure Capsule BSC2.17</p> <p><b>Policy Statement:</b></p> <p>I. Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered <b>investigational</b> for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders.</p>	<p>Ingestible pH and Pressure Capsule BSC2.17</p> <p><b>Policy Statement:</b></p> <p>I. Measurement of gastrointestinal transit times, including gastric emptying and colonic transit times, using an ingestible pH and pressure capsule is considered <b>investigational</b> for the evaluation of suspected gastroparesis, constipation, or other gastrointestinal motility disorders.</p>